IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

JOANNA MCCOY, et al. *Plaintiffs*, v. BIOMET ORTHOPEDICS, LLC, et al., *Defendants*.	Civil Action No. ELH-12-1436

MEMORANDUM OPINION

This product liability case concerns an allegedly defective orthopedic device used for hip replacements. Defendants Biomet Orthopedics, LLC; Biomet Manufacturing Corp.; and Biomet U.S. Reconstruction, LLC (collectively, "Biomet") designed and manufactured metal-on-metal hip implant systems, including the M2a-Magnum™ (the "Magnum" or the "Biomet device"). Plaintiff Joanna McCoy was implanted with the Biomet device in 2007, during an operation for a replacement of her right hip. ECF 96-3 at 22.

In 2012, Dr. McCoy, a veterinarian, and her husband, plaintiff Kenneth Burgwin, filed suit against Biomet. They allege that the Biomet device was defective and caused Dr. McCoy substantial injuries, necessitating subsequent hip replacement surgeries, *i.e.*, "revision" surgeries. *See* ECF 1; ECF 96-1 at 8 n.3.

In 2019, after consolidated pretrial proceedings, discussed *infra*, plaintiffs filed an amended complaint, containing multiple counts. ECF 43 (the "Amended Complaint").[1] In

[1] In the Amended Complaint, plaintiffs sued Biomet Orthopedics, LLC; Zimmer Biomet Holdings, Inc.; Biomet Manufacturing Corp.; and Biomet U.S. Reconstruction, LLC. ECF 37. However, during the consolidated pretrial proceedings, all Biomet corporate entities were dismissed from suit, except Biomet, Inc.; Biomet Orthopedics, LLC; Biomet Manufacturing Corp.;

particular, plaintiffs allege that the metal-on-metal design of these implants caused the device to corrode, releasing metallic debris into the bloodstream that killed surrounding tissue and bone. Further, plaintiffs assert that Biomet advertised these products as safe, despite knowing that they were defective.

This case was one of many filed against Biomet. On October 2, 2012, pursuant to 28 U.S.C. § 1407, the Joint Panel on Multidistrict Litigation ("JPML") consolidated all cases involving Biomet's Magnum and the M2a-38 into a Multi-District Litigation action ("MDL") for coordinated pretrial proceedings. *See In re: Biomet M2A Magnum Hip Implant Prods. Liab. Litig.*, 896 F. Supp. 2d 1339, 1340 (J.P.M.L. 2012). MDL-2391 was assigned to Judge Robert Miller, Jr. of the United States District Court for the Northern District of Indiana.[2] *Id.* On September 19, 2018, after extensive pretrial proceedings, the *McCoy* matter was returned from the MDL to the District of Maryland as part of the first remand group. MDL-2391, MDL Dkt. No. 3724; *see* ECF 22.[3]

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and Biomet U.S. Reconstruction, LLC. *See* MDL-2391, Dkt. No. 444. Accordingly, Zimmer Biomet Holdings, Inc. is no longer a defendant.

In the answer to the Amended Complaint, Biomet states that Biomet Manufacturing, LLC was "incorrectly named" in the Amended Complaint as Biomet Manufacturing Corp. ECF 48 at 1. However, the aforementioned order of the MDL court referenced Biomet Manufacturing Corp.

[2] The docket for MDL-2391 can be accessed at *MDL 2391, In Re: Biomet M2A Magnum Hip Implant Products Liability Litigation*, UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF INDIANA, https://www.innd.uscourts.gov/mdl-2391 (last accessed January 13, 2021).

[3] Several other lawsuits against Biomet were assigned to me. Plaintiffs moved to consolidate their suit with another case returned from the MDL court. ECF 54. I denied that motion. ECF 79; ECF 80. However, I did consolidate other Biomet cases.

The cases of *Fowler v. Biomet Orthopedics, LLC*, ELH-19-2931 and *Soustek v. Biomet Mfg. Corp.*, ELH-15-1890 settled in 2019. Both *Ringley v. Biomet, Inc.*, ELH-17-747 and *Laughlin v. Biomet, Inc.*, ELH-14-1645 settled in June 2020. On January 6, 2021, a notice of settlement was filed in the cases of *Harris v. Biomet Orthopedics, LLC*, ELH-18-3924, *Harbold v. Biomet Orthopedics, LLC*, ELH-18-3925, and *Kandel v. Biomet Orthopedics, LLC*, ELH-18-3926.

Plaintiffs filed the Amended Complaint in 2019, after the suit was returned to this Court. They lodge claims exclusively under Maryland law. In Count I, plaintiffs assert a claim for "Strict Product Liability," alleging, *inter alia*, that the Magnum contained manufacturing defects and design defects, and that Biomet's failure to warn McCoy of the risks posed by the Magnum caused her harm. ECF 43 ¶ 102(a), (b), (d); *see id.* at 24. In Count II, plaintiffs allege negligence as to Biomet's "design, manufacture, testing, inspection, labeling, promotion, marketing, and sale" of the Magnum. *Id.* ¶ 111. Count III lodges a claim for "Breach of Implied Warranties," asserting that the defendants breached the implied warranty of merchantability. *See id.* ¶¶ 118-24. And, plaintiffs assert claims for "Breach of Express Warranty" (Count IV), *id.* ¶¶ 125-29, punitive damages (Count V), *id.* ¶¶ 130-38, and loss of consortium (Count VI). *Id.* ¶¶ 139-40.[4] Jurisdiction is founded on diversity of citizenship under 28 U.S.C. § 1332. It is undisputed that Maryland law governs plaintiffs' claims.

Pursuant to Fed. R. Civ. P. 702 and *Daubert v. Merrell Dow Pharmaceuticals*, Inc., 509 U.S. 579, 597 (1993), Biomet has moved to exclude the opinion evidence offered by two of plaintiff's expert witnesses. The motion to exclude the opinions of Jeffrey F. Shapiro, M.D. is docketed at ECF 94, supported by a memorandum of law. ECF 94-1 (collectively, the "Shapiro Motion"). And, defendants' motion to exclude the opinions of Frank Ebert, M.D. is docketed at ECF 95, supported by a memorandum of law. ECF 95-1 (collectively, the "Ebert Motion").

As discussed, *infra*, Judge Hazel recently granted in part and denied in part Biomet's motion for summary judgment in *Morris v. Biomet, Inc.*, ___ F. Supp. 3d ___, GJH-18-2440, 2020 WL 5849482 (D. Md. Sept. 30, 2020).

[4] The Amended Complaint does not contain a Count V; it skips from Count IV to Count VI. *See* ECF 43 at 29-30. And, the punitive damages claim and the loss of consortium claim are both labeled "Count VI." *Id.* at 30, 33. I shall refer to the punitive damages claim as Count V and the loss of consortium claim as Count VI.

Plaintiffs oppose both motions. ECF 100 (opposition to the Ebert Motion); ECF 101 (opposition to the Shapiro Motion). Biomet has replied. ECF 104 (as to the Ebert Motion); ECF 105 (as to the Shapiro Motion). All submissions, except ECF 105, are accompanied by exhibits. Neither side has requested a hearing and no hearing is needed. Local Rule 105.6.

Biomet has also moved for summary judgment on all counts (ECF 96), supported by a memorandum of law. ECF 96-1 (collectively, the "Summary Judgment Motion"). Plaintiffs oppose the Summary Judgment Motion. *See* ECF 103. Biomet has replied. ECF 106. All submissions are accompanied by exhibits.

In addition, plaintiffs have filed a cross-motion for partial summary judgment as to several of the affirmative defenses that Biomet asserted in its answer to the Amended Complaint. ECF 97 ("Plaintiffs' Motion"). Biomet's opposition is docketed at ECF 102. Plaintiffs have not replied and the time to do so has expired.

While the motions were pending, Biomet filed a notice of supplemental authority (ECF 107) to draw the court's attention to a recent decision authored by Judge George Hazel of this Court in a case returned from MDL-2391. *See Morris v. Biomet, Inc.*, ___ F. Supp. 3d ___, GJH-18-2440, 2020 WL 5849482 (D. Md. Sept. 30, 2020). Thereafter, plaintiffs filed a similar submission, highlighting recent decisions in *Fitzsimmons v. Biomet Orthopedics, Inc.*, No. 219CV182FTM29NPM, 2020 WL 6784236, at *1 (M.D. Fla. Nov. 18, 2020); *Bayes v. Biomet, Inc.*, No. 4:13-CV-00800-SRC, 2020 WL 5095346, at *13 (E.D. Mo. Aug. 28, 2020); and *Nicholson v. Biomet, Inc.*, 18-CV-3057-CJW-KEM, 2020 WL 3399899 (N.D. Iowa Mar. 6, 2020).

No hearing is necessary to resolve the summary judgment motions. *See* Local Rule 105(6). For the reasons that follow, I shall grant in part and deny in part the Shapiro Motion; grant the

Ebert Motion; grant in part and deny in part Biomet's Summary Judgment Motion; and grant in part and deny in part Plaintiffs' Motion.

I. Background

A. Factual Background[5]

1.

The hip joint, also referred to as the hip, connects the thigh bone (the femur) to the pelvis. ECF 43, ¶ 13; ECF 48, ¶ 13. It operates like a ball and socket: the femoral head, a ball-like structure that sits atop the femur bone, rotates within the cupped surface at the bottom of the pelvis, *i.e.*, the acetabulum, which functions as a socket. *See* ECF 43, ¶ 13; ECF 48, ¶ 13. The hip joint is lined with cartilage, lubricating tissue that cushions the femur and the acetabulum as the joint bears weight. *See* ECF 43, ¶ 13; ECF 48, ¶ 13. With every step taken, the hip joint moves: "It flexes, extends, and moves out to the side." ECF 103-6 at 10.

Over time, the cartilage in the hip joint can wear down, leaving bone to rub against bone. *Id*. This process can cause swelling, inflammation, and pain, which are symptoms associated with arthritis. *Id.*

Total hip replacement surgery, also known as total hip arthroplasty, entails replacing the body's natural joint with an artificial one. *See* ECF 43, ¶ 14; ECF 48, ¶ 14; ECF 103-6 at 10. Damaged bone and cartilage from the socket of the hip joint, along with part of the femur, is replaced with an implant. *See* ECF 43, ¶ 14; ECF 48, ¶ 14; ECF 103-6 at 10. A hip implant may be made of different materials, including metal alloys, polyethylene (a type of plastic), or ceramic

[5] The factual background is largely drawn from the exhibits attached to the motions, as well as from undisputed allegations in the Amended Complaint.

material. *See* ECF 43, ¶ 14; ECF 48, ¶ 14. Implants are designed to restore the femoral head's smooth rotation and natural leg movement. *See* ECF 43, ¶ 14; ECF 48, ¶ 14; ECF 103-6 at 10

The Biomet device at issue has three components: an acetabular cup (also referred to as a shell), a femoral head, and a taper insert. ECF 96-1 at 11. During total hip replacement surgery using such a device, a surgeon inserts the acetabular cup into the hip socket. ECF 103-6 at 10. The surgeon also removes the "diseased ball part" of the femur and replaces it with the femoral head and the taper insert, which fit into the acetabular cup. *See id.*; ECF 96-1. The Magnum is affixed to a metallic femoral stem, a separate device, which is fitted into the femur. ECF 103-6; *see* ECF 96-5 at 4. Thus implanted, the femoral head functions as a ball within the acetabulum, allowing for natural leg movement. *Id.*

The Magnum's acetabular cup and femoral head are made out of cobalt chrome molybdenum, a metal alloy. ECF 96-1 at 11; ECF 96-6 at 2. The taper insert is made of a titanium alloy. For this reason, the Magnum is known as a metal-on-metal ("MoM") device or system. *See* ECF 96-13 at 11; ECF 103-6 at 2. Devices that contain a polyethylene (plastic) liner between the femoral head and the acetabular cup, known as metal-on-polyethylene devices ("MoP"), are a prominent alternative to the MoM design. *See* ECF 43, ¶ 14; ECF 96-1 at 11; ECF 103-6 at 8.

Like all Magnum devices distributed to medical providers, the Magnum device implanted into Dr. McCoy included "Instructions for Use" ("IFU"). ECF 96-1 at 12; ECF 96-6 at 2. The top of the IFU reads: "Attention Operating Surgeon." ECF 96-6 at 2. Among other things, the IFU contains sections titled "Warnings," "Precautions," and "Possible Adverse Effects." *Id.* The section on Warnings states, in relevant part, *id.*:

> Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation may lead to excessive wear and/or failure

of the implant or procedure.

The section on Possible Adverse Effects lists the following, in relevant part, *id.*:

1. Material sensitivity reactions. Implantation of foreign material in tissues may result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant. A low incidence of metal hypersensitivity has been reported with failed metal on metal implants. The clinical relevance of these findings is unclear, and it is not known whether metal hypersensitivity causes implant failure.

2. Early or late postoperative infection and allergic reaction.

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4. Loosening or migration of the implants may occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.

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10. Fretting and crevice corrosion may occur at interfaces between components.

11. Wear and/or deformation of articulating surfaces.

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15. Elevated metal ion levels have been reported with metal-on-metal articulating surfaces. Although mechanical testing demonstrates that metal-on-metal articulating surfaces produce a relatively low amount of particles, the total amount of particulate produced in vivo throughout the service life of the implants remains undetermined. The long-term biological effects of the particulate and metal ions are unknown.

2.

Plaintiff began experiencing pain in her right hip around 2006. ECF 96-3 at 3.[6] Beginning in October 2006, she met with multiple doctors, including orthopedic specialists. *See id.* at 7-8, 12-15. She was diagnosed with arthritis in both her right and left hip. *Id.* at 7.

Dr. McCoy first saw orthopedic surgeon Dr. Marc Brassard in Annapolis, Maryland in April 2007. *Id.* at 16. At that visit, plaintiff was five feet, five inches in height and weighed 192 pounds. *Id.* Dr. Brassard's notes indicate that plaintiff reported constant pain in her right hip. *Id.* During a visit in October 2007, Dr. Brassard recorded an impression of plaintiff as having bilateral hip arthritis. *Id.* at 17. He identified total hip replacement surgery as a treatment option for her right hip. *See id.* at 9-10. A month and a half later, Dr. McCoy indicated that she wished to proceed with surgery. *Id.* at 10.

According to the transcript of Dr. McCoy's deposition (ECF 96-4, "McCoy Tr."), plaintiff had consulted with other surgeons about hip replacement surgery. ECF 96-4 at 4, McCoy Tr. 54-55. The other surgeons recommended MoP implants. *Id.* Dr. Brassard, however, recommended a MoM device. *Id.* Plaintiff understood from her conversation with Dr. Brassard that a MoP device might require a revision surgery in fifteen to twenty years, whereas a MoM device would "probably last the rest of [her] life." *Id.*, McCoy Tr. 55. Dr. Brassard did not specifically recommend the MoM device of any particular manufacturer or indicate which manufacturer's device he planned to use. *Id.* at 5, McCoy Tr. 60. Plaintiff trusted Dr. Brassard to choose the right device for her. *Id.*

[6] Throughout the Memorandum Opinion, any reference to "plaintiff" pertains only to Dr. McCoy, not her spouse.

On December 6, 2007, Dr. Brassard performed a total right hip replacement with the Magnum on Dr. McCoy. *Id.* at 22. At his deposition (ECF 96-5, "Brassard Tr."), Dr. Brassard could not specifically recall whether he had previously read the Magnum's IFU. *Id.* at 31. But, he testified that, in general, he would review materials like the IFU. *Id.* In addition, Dr. Brassard testified that at the time of plaintiff's surgery in 2007, he was independently aware of some of the "Possible Adverse Effects" indicated in the IFU, including "material sensitivity reactions," "elevated metal ions" of cobalt and chromium, and "postoperative infection." *Id.* at 37-39.

Plaintiff had a follow-up appointment with Dr. Brassard three months after the surgery. ECF 96-3 at 12. According to Dr. Brassard's notes, plaintiff was doing well. *Id.* Her right hip showed "good alignment with no evidence of loosening" of the implant. *Id.*

In May 2008, Dr. McCoy saw Dr. Brassard a few days after experiencing a fall. *Id.* at 20. Dr. McCoy had "landed directly on her knee," which "pushed up on her hip." *Id.* She was experiencing pain in her right hip. *Id.* Dr. Brassard observed that her right hip still showed "good alignment." *Id.*

Plaintiff attended a scheduled check-up with Dr. Brassard on October 22, 2008, over ten months after her surgery. *Id.* at 24. According to Dr. Brassard, x-rays showed that the Magnum continued to demonstrate "good alignment," with "no evidence of loosening." *Id.*

Over the following two years, Dr. McCoy met with several doctors regarding a range of issues related to musculoskeletal pain, including but not limited to pain in both of her hips, back pain, sciatic joint pain, fibromyalgia, and psoriatic arthritis. *See id.* at 3-5, 27-31. At an appointment on July 10, 2009, plaintiff reported that the pain for which she was seeking treatment was distinct from the pain that led her right hip replacement. *Id.* at 4.

Plaintiff met with Dr. Brassard again on March 22, 2010, and reported renewed right hip pain among various other issues. *Id.* at 21. The medical record from that visit is incomplete; it indicates that Dr. Brassard recorded his observations about the alignment of her right hip, but cuts off before the completion of that portion of the record. *See id.*

Dr. Ebert, an orthopedic surgeon at MedStar Union Memorial Hospital in Baltimore, examined plaintiff for the first time on April 17, 2010. *See* ECF 96-3 at 10; ECF 95-2. Dr. Ebert observed that plaintiff had "tremendous restriction of motion about the right hip" and that her right leg was three-quarters of an inch shorter than her left. ECF 96-3 at 10. He also noted: "[Plaintiff] is followed by Dr. Brassard and he has evaluated her from the infection stand point and this has been entirely negative." *Id.*

According to Dr. Ebert's notes, radiographs taken of plaintiff's right hip showed, in relevant part, ECF 96-3 at 10:

> [A] vertical orientation of the acetabular component consistent with loosening when compared to the immediate post-operative x-ray . . . . The cup is now changed in its position . . . . There also is radio lucency consistent with loosening around the acetabular component and in fact the patient has osteolysis of the medial calcar of the femur suggestive of the fact that she may also have a granulomatous reaction about her hip related to the metal on metal implant.

Based on his observations, Dr. Ebert recommended revision surgery on plaintiff's right hip. *Id.* He performed the revision surgery on May 10, 2010. *Id.* at 36. During the surgery, Dr. Ebert found purulence, *i.e.*, purulent fluid or pus, in plaintiff's right hip, which indicated the possible presence of infection. *Id.* at 34. The femoral stem was intact. *Id.* He removed the acetabular cup of the Magnum implant and replaced it with "an antibiotic-impregnated cement and a liner for an acetabular shell." *Id.*

Tests were conducted on the purulent fluid from plaintiff's right hip, which "showed no evidence of any growth." *Id.* Tests conducted on fluid drawn from plaintiff's hip six weeks after

the surgery similarly "showed no evidence of any growth." *Id.* Dr. Ebert's notes state, in relevant part: "[I]n light of this it was felt that the debris that was found that was purulent material was most likely debris from the metal-on-metal prosthetic device and not gross purulence." *Id.*

On March 1, 2011, Dr. Ebert performed a second revision surgery on plaintiff's right hip. *Id.* He replaced the Magnum's acetabular cup with a different product that contained a polyethylene liner. *Id.* Thereafter, plaintiff also underwent surgery for total left hip replacement, during which Dr. Ebert implanted an MPE device. *Id.* at 33.

Additional facts are discussed, *infra*.

B. Procedural History

As noted, on October 2, 2012, the JPML created MDL No. 2391 in the Northern District of Indiana, assigning Judge Miller to coordinate pretrial proceedings for all lawsuits alleging defects with Biomet's Magnum and a predecessor product. *See In re: Biomet*, 896 F. Supp. 2d at 1340 n.2, 1341. At the time, Biomet opposed centralization, arguing that "individualized, plaintiff-specific issues will predominate among the actions." *Id.* at 1339-40. But, the JPML rejected that contention. It observed that "'almost all injury litigation involves questions of causation that are case- and plaintiff-specific. Such differences have not been an impediment to centralization in the past.'" *Id.* at 1340 (quoting *In re Wright Med. Tech., Inc., Conserve Hip Implant Prods. Liab. Litig.*, 844 F. Supp. 3d 1371, 1372 (J.P.M.L. 2012)). And, it found that the "central issues in these cases may well be whether a common defect has led to the injuries alleged." *Id.* Thus, because the lawsuits "share factual questions concerning design, manufacture, marketing and performance of Biomet's M2A Magnum system," the JPML concluded that "centralization will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation[.]" *Id.*

By order of March 14, 2016, Judge Miller permitted any plaintiff whose case would have been subject to transfer to MDL No. 2391 to file his or her case directly in the Northern District of Indiana. MDL-2391, Dkt. No. 3096. As Judge Miller explained, permitting eligible plaintiffs to do so was intended to "eliminate delays associated with the transfer cases from other federal district courts to [the MDL] and to promote judicial efficiency." *Id.* at 2. However, direct filing was "contingent on the understanding that upon completion of all pretrial proceedings . . . th[e] court w[ould], pursuant to 28 U.S.C. § 1404(a), transfer the case to a federal district of proper venue, as defined by 28 U.S.C. § 1391, unless the parties expressly agree to an alternate venue." *Id.*

As mentioned, plaintiffs filed suit in this Court in 2012. ECF 1. The case was transferred to the MDL on October 23, 2012. ECF 21.

In the consolidated pretrial proceedings, the Plaintiffs' Executive Committee and Biomet each submitted expert opinion testimony. *In re Biomet M2a Magnum Hip Implant Prod. Liab. Litig.*, No. 3:12-MD-2391, 2017 WL 10845178, at *1 (N.D. Ind. Dec. 21, 2017). The expert evidence that the Executive Committee sought to admit included the opinions of Mari Truman, a biomedical engineer, and George S. Kantor, M.D., an orthopedic surgeon. *Id.* at *1, 10, 15. Plaintiffs designated Ms. Truman and Dr. Kantor as "general causation" experts pursuant to Fed. R. Civ. P. 26, as discussed *infra*.

According to Judge Miller, Ms. Truman opined, *id.* at 11:

> (1) [A]ll metal-on-metal devices are defectively designed; (2) metal-on-polyethylene devices are a reasonably safe alternative to metal-on-metal devices; (3) Biomet should have conducted additional testing of its metal-on-metal devices; (4) Biomet should have provided additional and more aggressive warnings to surgeons about the risks associated with its metal-on-metal devices; (5) Biomet downplayed the risks of its metal-on-metal devices; and (6) excessive metal ions cause certain clinical effects in patients with metal-on-metal devices.

Specifically, Ms. Truman's sixth opinion was that "Biomet's metal-on-metal devices can cause 'elevated metal ions with immune response complications ... and tissue necrosis.'" *Id.* at 14 (quoting MDL 2391, Dkt. No. 3387-2 at 86). In other words, Ms. Truman's proffered report described Biomet's MoM hip implants, including the Magnum, as prone to "excessive wear," which "produces elevated metal ions, which cause immune response complications and tissue necrosis." 2017 WL 10845178, at *14.

Biomet sought to exclude Ms. Truman's opinions under Rule 702 and *Daubert*, contending that they were not reliable and that Ms. Truman was not qualified to render them. *Id.* at 11. Judge Miller rejected Biomet's arguments and determined that all of Ms. Truman's opinions were admissible, noting that several of Biomet's challenges were directed to the weight, not the admissibility, of the evidence. *Id.* at 11-15. As to Ms. Truman's sixth opinion, Judge Miller ruled: "Ms. Truman can't testify as an expert on the clinical effects of metal ions, but she can permissibly rely on other experts' opinions that metal ions cause clinical effects to support her opinion that metal-on-metal devices are unreasonably dangerous. . . . That's what she did in her report, so her opinion is admissible." *Id.* at 15.

Biomet also filed a *Daubert* motion to exclude Dr. Kantor's opinions. *Id.* Dr. Kantor opined in his report, *id.*:

> (1) [M]etal-on-metal devices generally, and Biomet's metal-on-metal devices specifically, are defectively designed and their risks outweigh their benefits; (2) Biomet didn't conduct sufficient testing and monitoring of its devices; (3) Biomet's instructions for use were inadequate; and (4) elevated metal ions might cause cancer.

Judge Miller ruled that Dr. Kantor's opinions as to the design defects and associated risks of Biomet devices specifically were inadmissible, but that Dr. Kantor's opinions as to the design defects and associated risks of MoM devices generally were admissible. *Id.* at 19. Judge Miller also excluded the opinion "about the sufficiency of Biomet's testing and clinical studies." *Id.* But,

he allowed Dr. Kantor's opinions regarding the Biomet devices' IFUs and the effects of elevated metal ions. *Id.*

In the MDL, Biomet also moved for summary judgment as to some of the product liability claims, on the basis of a "'state of the art' theory.'" *In re Biomet M2A Magnum Hip Implant Prod. Liab. Litig.*, No. 3:12-MD-2391, 2018 WL 776776, at *1 (N.D. Ind. Feb. 8, 2018). According to Biomet, there were no genuine disputes of material fact regarding its state-of-the-art assertions. *Id.* Biomet contended, *id.*:

> [I]ts metal-on metal devices were 'state of the art' from the time they were first designed, manufactured, and marketed until 2013 (when Biomet stopped producing metal-on metal devices), or at least 2011 (when the FDA issued a public notice of concern regarding metal-on metal hip implants)[.]

Judge Miller denied defendants' motion but declined to reach the merits. He reasoned that a ruling on the merits would require synthesizing "the state-of-the-art law of nineteen different states," which would "indefensibly slow the process in this docket." *Id.* at 3.

Therefore, Judge Miller transferred plaintiffs' suit back to this Court on September 19, 2018. MDL-2391, Dkt. No. 3724; *see* ECF 22. In the transfer order, Judge Miller explained that of the approximately 3,000 cases that were part of the MDL, 90% had settled as part of a master settlement agreement reached in 2014. *See* MDL-2391, Dkt. No. 3738 at 2-3, 6; *see also* MDL-2391, Dkt. No. 1317 (Master Settlement Agreement). The remaining cases were being sent to their proper districts for trial. MDL-2391, Dkt. No. 3738 at 13. Further, Judge Miller observed, *id.*:

> Any case might present its own atypical need, but for the most part, here is what will be left to do after remand: (1) additional, non-duplicative, case-specific depositions; (2) disclosure of case-specific experts, service of case-specific expert reports, and case-specific expert depositions; (3) any motions addressing the testimony of case-specific experts; (4) any motions (or, perhaps, trial objections) directed to the recorded trial testimony of the plaintiffs' generic experts; (5) any

other motions addressing the testimony of generic or case-specific experts; and (6) any summary judgment motions.

Since the case was returned to this Court, both sides have gathered opinion evidence from expert witnesses. As noted, plaintiffs seek to present expert testimony from Dr. Ebert and Dr. Shapiro. Biomet has also retained three experts in this litigation: Steven Kurtz, PH.D., a biomedical engineer; Thomas Fleeter, M.D.; and Thomas W. Bauer, M.D., PH.D., a pathologist. The reports produced by Dr. Kurtz and Dr. Bauer have each been submitted as exhibits. *See* ECF 96-13 (Dr. Kurtz's report); ECF 96-15 (Dr. Bauer's report). Dr. Fleeter's report appears not to have been successfully appended as an exhibit. ECF 96-14 contains a Declaration of Thomas Fleeter, M.D., which references an expert report. But, there is no such report among the exhibits.

The pending motions followed. Thereafter, Biomet filed a notice of supplemental authority to draw the court's attention to *Morris*, 2020 WL 5849482. ECF 107. Plaintiffs filed a similar submission, highlighting recent decisions in *Fitzsimmons v. Biomet Orthopedics, Inc.*, No. 219CV182FTM29NPM, 2020 WL 6784236, at *1 (M.D. Fla. Nov. 18, 2020), *Bayes v. Biomet, Inc.*, No. 4:13-CV-00800-SRC, 2020 WL 5095346, at *13 (E.D. Mo. Aug. 28, 2020), *Nicholson v. Biomet, Inc.*, 18-CV-3057-CJW-KEM, 2020 WL 3399899 (N.D. Iowa Mar. 6, 2020). Each case involves distinct fact patterns.

II. The *Daubert* Motions

According to plaintiffs' Rule 26 disclosures, which Biomet has submitted as an exhibit to its Summary Judgment Motion (ECF 96-9), plaintiffs seek to introduce evidence from five experts. *Id.* Plaintiffs have designated three of their experts as "general causation" experts and two as "specific causation" experts. *Id.*

"For specific causation, the plaintiff must 'demonstrate that the substance actually caused injury in her particular case.'" *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod.*

Liab. Litig. (No II) MDL 2502, 892 F.3d 624, 642–43 (4th Cir. 2018) (citation omitted). "Specific causation is often distinguished from general causation, which refers to the more general issue of whether a substance has *the potential to cause* the plaintiff's injury." *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245, 1249 n.1 (11th Cir. 2010) (emphasis added); *see In re Lipitor*, 892 F.3d at 658-59 (discussing *Guinn*).

The three general causation experts identified by plaintiffs are Mari Truman; George Kantor, M.D.; and Francis H. Gannon, M.D., a Professor of Pathology & Immunology and Orthopedic Surgery. *Id.* Each expert has produced a written report and is expected to testify via previously recorded deposition testimony. *Id.*

In addition, plaintiffs have designated Dr. Shapiro and Dr. Ebert, both of whom are orthopedic surgeons, as "specific causation experts." *Id.* Dr. Shapiro's opinion evidence is contained in a four-page report dated May 12, 2019 (ECF 94-2), and in the transcript of his deposition, which took place on February 27, 2020. ECF 94-3 ("Shapiro Tr."). In his report, which is described further below, Dr. Shapiro opines that Dr. McCoy experienced "'[a]dverse tissue reaction' to metal debris,'" which was "the result of the breakdown and failure of the metal-on-metal [Magnum]." ECF 94-2 at 5. According to Dr. Shapiro, Dr. McCoy's revision surgeries "were required as a result of the failure of" her Magnum implant. *Id.* And, the report states: "There is no other explanation." *Id.*

As indicated, Dr. Ebert was plaintiff's treating physician; he performed two revision surgeries on plaintiff's right hip. Dr. Ebert's opinion evidence is contained in a one-page affidavit, dated February 9, 2015 (ECF 95-2), and in the transcript of his deposition, which took place on September 15, 2016. ECF 95-3 ("Ebert Tr."). In his affidavit, Dr. Ebert opines that Dr. McCoy's

revision surgery of May 10, 2010, "was more likely than not due to symptoms linked to the metal-on-metal design of [her] Biomet device." ECF 95-2.

As noted, Biomet has moved to exclude the opinions of both doctors, pursuant to Rule 702 and *Daubert*, 509 U.S. 579.

A. Legal Standard

1.

Pursuant to Rule 104(a) of the Federal Rules of Evidence ("F.R.E."), the court is responsible for determining "preliminary questions concerning the qualification of a person to be a witness" and "the admissibility of evidence." This includes the admissibility of expert testimony under F.R.E. 702.

In *Daubert*, 509 U.S. at 597, the Supreme Court made clear that scientific evidence is admissible under F.R.E. 702 if "it rests on a reliable foundation and is relevant." In *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999), the Supreme Court extended the principles pertaining to scientific expert testimony to all expert testimony requiring technical or specialized knowledge. Notably, the party seeking to present expert testimony must establish its admissibility by a preponderance of the evidence. *See Cady v. Ride-Away Handicap Equipment Corp.*, 702 Fed. App'x 120, 124 (4th Cir. 2017) (citing *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001)); *Maryland Casualty Co. v. Therm-O-Disc., Inc.*, 137 F.3d 780, 783 (4th Cir. 1998); *Fireman's Fund Ins. Co. v. Tecumseh Prods. Co.*, 767 F. Supp. 2d 549, 553 (D. Md. 2011); *Casey v. Geek Squad ® Subsidiary Best Buy Stores, L.P.*, 823 F. Supp. 2d 334, 340 (D. Md. 2011).

Rule 702 of the F.R.E. governs expert testimony. It provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Pursuant to Rule 702, a properly qualified expert witness may testify regarding technical, scientific, or other specialized knowledge in a given field if the testimony would assist the trier of fact in understanding the evidence or to determine a fact in issue, and the testimony is both reliable and relevant. *United States v. Young*, 916 F.3d 368, 379 (4th Cir. 2019). The rule "was intended to liberalize the introduction of relevant expert evidence." *Westberry v. Gislaved Gummi AB*, 178 F. 3d 257, 261 (4th Cir. 1999).

Under Rule 702, the district judge "must ensure that the expert is qualified and that the expert's testimony is both relevant and reliable." *United States v. Smith*, 919 F.3d 825, 835 (4th Cir. 2019) (citing *Daubert*, 509 U.S. at 589). The trial court serves a "gatekeeping role" by making pretrial determinations "of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. This gatekeeper role helps to ensure that the expert's testimony "rests on a reliable foundation and is relevant to the task at hand." *Id.* at 597; *see Lord & Taylor, LLC v. White Flint, L.P.*, 849 F.3d 567, 577 (4th Cir. 2017).

However, the Supreme Court did not intend the gatekeeper role to "supplant the adversary system or the role of the jury: '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'" *Allison v. McGhan Medical Corp.*, 184 F.3d 1300, 1311–12 (11th Cir. 1999) (quoting *Daubert*, 509 U.S. at 596); *see United States v. Moreland*, 437 F. 3d 424, 431 (4th Cir. 2006) (recognizing that "expert testimony is subject to testing by vigorous cross-

examination, presentation of contrary evidence, and careful instruction on the burden of proof"). Thus, the district court "is not intended to serve as a replacement for the adversary system, and consequently, the rejection of expert testimony is the exception rather then the rule." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Production Liab. Litig. (No. II)*, 892 F.3d 624, 631 (4th Cir. 2018) (citation and quotation marks omitted).

As noted, to be admissible, scientific evidence must be both reliable and relevant. *Daubert*, 509 U.S. at 597. To be reliable, the testimony must be grounded "in the methods and procedures of science," and it must be something more than subjective belief or unsupported assumptions. *Id.* at 589–90; *see Belville v. Ford Motor Co.*, 919 F.3d 224, 232 (4th Cir. 2019); *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999). Moreover, the evidence or testimony must be relevant to the extent that it will "assist the trier of fact to understand the evidence or to determine a fact in issue." *Daubert* 509 U.S. at 591; *see also In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 631 (4th Cir. 2018); *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017); *United States v. Forrest*, 429 F.3d 73, 80–81 (4th Cir. 2005). An expert's testimony is relevant if it has "'a valid scientific connection to the pertinent inquiry.'" *Belville*, 919 F.3d at 232 (citation omitted).

Daubert articulated five factors that the trial court should consider in evaluating the reliability of an expert's reasoning or methodology: (1) whether the particular scientific theory has been or can be tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; (4) whether there are standards controlling the method; and (5) whether the technique has gained general acceptance in the relevant scientific community. *Daubert*, 509 U.S. at 593–94; *see Belville*, 919 F.3d at 233; *United States v. Crisp*, 324 F.3d 261, 265–66 (4th Cir. 2003).

Notably, the factors are "'not exhaustive.'" *Belville*, 919 F.3d at 233 (citation omitted). Moreover, the evaluation "is always a flexible one . . . ." *Oglesby*, 190 F.3d at 250. As a whole, the factors are meant to ensure that "an expert, whether basing his testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co.*, 526 U.S. at 152. Thus, the factors are meant to be "helpful, not definitive," and not all factors necessarily apply in a given case. *Id.* at 151; *see Nease*, 848 F.3d at 229. Indeed, the Supreme Court has said that the factors are not a "checklist." *Kumho Tire Co.*, 526 U.S. at 150.

With regard to an expert's qualifications, the Advisory Committee's notes to Rule 702 provide that experience alone, or in conjunction with "other knowledge, skill, training or education," can provide sufficient foundation for expert testimony. *See Kumho Tire Co.*, 526 U.S. at 156 (stating that "no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."). On the other hand, an expert witness may not offer an opinion where the subject matter goes beyond the witness's area of expertise. *See Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994); *see also Smith v. Central Admixture Pharm. Servs., Inc.*, AW–07–3196, 2010 WL 1137507, at *3 (D. Md. Mar. 19, 2010) ("It is well established that 'general expertise is not sufficient to qualify [an expert] to testify on a matter that requires particularized knowledge, training, education, or experience.'" (quoting *Fitzgerald v. Smith & Nephew Richards, Inc.*, JFM-95-3870, 1999 WL 1489199, at *3 (D. Md. Dec. 30, 1999), *aff'd sub nom. Fitzgerald v. Smith & Nephew, Inc.*, 11 F. App'x 335 (4th Cir. 2001))).

The trial court "should meticulously focus on the expert's principles and methodology, and not on the conclusions that they generate." *McDowell v. Brown*, 392 F.3d 1283, 1298 (11th Cir. 2004); *see Bresler*, 855 F.3d at 195. Moreover, expert testimony need not be "'irrefutable or

certainly correct'" in order to be admissible. *Moreland*, 437 F. 3d at 431 (citation omitted); *see Daubert*, 509 U.S. at 596; *Bresler v. Wilmington Trust Co.*, 855 F.3d 178, 195 (4th Cir. 2017); *Westberry*, 178 F.3d at 261. Therefore, "'questions regarding the factual underpinnings of the [expert witness'] opinion affect the weight and credibility' of the witness' assessment, 'not its admissibility." *Bresler*, 855 F.3d at 195 (citation omitted).

But, a court should exclude testimony based on "belief or speculation," *Oglesby*, 190 F.3d at 250, or when not supported by the record. *See Bryte ex rel. Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005); *Tyger Const. Co. v. Pensacola Const. Co.*, 29 F.3d 137, 142 (4th Cir. 1994); *Casey*, 823 F. Supp. 2d at 340. Moreover, "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Similarly, a court may exercise its "discretion to find that there is 'simply too great an analytical gap between the data and the opinion proffered.'" *Pugh v. Louisville Ladder, Inc.*, 361 F. App'x 448, 454 n.4 (4th Cir. 2010) (quoting *Joiner*, 522 U.S. at 146).

Further, proposed testimony that concerns matters within the common knowledge and experience of a lay juror does not pass muster. *United States v. Dorsey*, 45 F.3d 809, 814 (4th Cir. 1995); *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993). "While the fit between an expert's specialized knowledge and experience and the issues before the court need not be exact . . . an expert's opinion is helpful to the trier of fact, and therefore relevant under Rule 702, 'only to the extent the expert draws on some special skill, knowledge or experience to formulate that opinion.'" *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 392–393 (D. Md. 2001) (quoting *Ancho v. Pentek Corp.*, 157 F.3d 512, 518 (7th Cir. 1998)).

In addition, Rule 702 does not relieve the party seeking admission of meeting the requirements of other applicable rules. This includes Rule 403's instruction that evidence may be excluded for undue prejudice, confusion of the issues, or a potential to mislead the jury. *Casey*, 823 F. Supp. 2d at 341; *see Westberry*, 178 F.3d at 261 ("[G]iven the potential persuasiveness of expert testimony, proffered evidence that has a greater potential to mislead than to enlighten should be excluded.").

2.

Of relevance here, Fourth Circuit case law establishes particular rules for assessing the reliability of expert testimony regarding medical causation under Rule 702. The method, or technique, for rendering an opinion regarding the cause of a medical problem is commonly referred to as a "differential diagnosis." *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999). This "standard scientific technique" involves "identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Id.* (citing *Baker v. Dalkon Shield Claimants Trust*, 156 F.3d 248, 252–53 (1st Cir.1998)); *see Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 200 (4th Cir. 2001) (discussing *Westberry*).

In *Westberry*, 178 F.3d 257, the Court "held that a *reliable* differential diagnosis provides a valid foundation for an expert opinion under Rule 702." *Cooper*, 259 F.3d at 200 (emphasis in original). The *Westberry* Court said, 178 F.3d at 262: "[T]ypically, though not invariably," a reliable differential diagnosis "is performed 'after physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests . . . .'" (citation omitted).

Generally, a reliable differential diagnosis "is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the

most likely." *Id.* (collecting cases). "'Although a reliable differential diagnosis need not rule out all possible alternative causes, it must at least consider other factors that could have been the sole cause of the plaintiff's injury.'" *In re Lipitor*, 892 F.3d at 644 (quoting *Guinn*, 602 F.3d at 1253). Moreover, an expert offering a differential diagnosis "'must provide a reasonable explanation as to why he or she has concluded that any alternative cause suggested by the defense was not the sole cause.'" *In re Lipitor*, 892 F.3d at 644 (quoting *Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 179 (6th Cir. 2009)).

B. The Ebert Motion

During discovery plaintiffs identified Dr. Ebert, one of Dr. McCoy's treating physicians, as an expert, pursuant to Rule 26(a)(2). ECF 96-9 at 3. The disclosure states, in relevant part: "Dr. Ebert is expected to testify as a specific causation expert consistent with the diagnosis, care, and treatment contained in Plaintiff's medical records and consistent with his July 28, 2016 deposition testimony." *Id.* at 3-4.[7] Dr. Ebert did not provide a written report.

During discovery, however, plaintiffs produced a one-page affidavit prepared by Dr. Ebert for purposes of this litigation. *See* ECF 95-2. The affidavit, dated February 9, 2015, contains the caption for this case while part of the MDL. *Id.* The affidavit provides, in full, *id*:

> 1. I am an orthopedic surgeon based in Baltimore, Maryland.
>
> 2. On or about May 10, 2010, I performed a right-side hip revision surgery on my patient Joanna McCoy, who also is the plaintiff in the above legal proceeding.
>
> 3. In the revision operative report where I removed the patient's failed Biomet Magnum hip device, I described encountering a "large amount of purulent fluid" from the hip joint.

[7] As noted, the transcript of Dr. Ebert's deposition is dated September 15, 2016. *See* ECF 100-3. Thus, it appears that plaintiffs erred in their Rule 26 disclosure by referencing "July 28, 2016 deposition testimony."

> 4. Furthermore, the pathology report for the revision surgery describes bone and tissue with "necrosis, granulation, acute and chronic inflammation." I also examined the patient prior to revision on April 17, 2010, and found no evidence of infection.
>
> 5. Based upon my professional training and experience as an orthopedic surgeon, it is within a reasonable degree of medical certainty that the above revision surgery was more likely than not necessary due to symptoms linked to the metal-on-metal design of my patient's Biomet device.[8]

Dr. Ebert was questioned by defense counsel about this affidavit at his 2016 deposition.

Biomet seeks to exclude Dr. Ebert's "later-formed causation opinions," expressed in his affidavit and in his deposition testimony, for two reasons. ECF 95-1 at 1. First, Biomet contends that Dr. Ebert's opinions are inadmissible because they were not included in plaintiffs' Rule 26 disclosure as to expert witnesses. And, defendants argue that Dr. Ebert's opinions, as expressed both in his affidavit and in his deposition testimony, are unreliable and, thus, inadmissible under Rule 702.

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[8] As indicated, Dr. Ebert's affidavit sets forth his opinion "within a reasonable degree of medical certainty." ECF 95-2. However, Rule 702 and Rule 703 "require a reliable methodology and reliable data but nowhere require a reasonable degree of medical certainty." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 751 (3d Cir. 1994) (citing, *inter alia*, *Daubert*, 509 U.S 587-88; *United States v. Cyphers*, 553 F.2d 1064, 1072 (7th Cir. 1977), *cert. denied* 434 U.S. 843 (1977)); *see also Samuel v. Ford Motor Co.*, 112 F. Supp. 2d 460, 470 (D. Md. 2000) (stating that the Federal Rules of Evidence do not require an expert to "affirmatively state that the opinion is held to a 'reasonable degree of certainty or probability'"), *aff'd sub nom. Berger v. Ford Motor Co.*, 95 F. App'x 520 (4th Cir. 2004).

Federal law controls the determination of admissibility. But, it bears mentioning that, under Maryland law, an expert's opinion must be held to a "'reasonable degree of medical probability . . . .'" *Am. Radiology Servs., LLC v. Reiss*, 470 Md. 555, 580, 236 A.3d 518, 532 (2020) (citation omitted). An expert witness is not required to base his opinion upon a reasonable degree of medical certainty. *Id.*; *see Rite Aid Corp. v. Levy-Gray*, 162 Md. App. 673, 711, 876 A.2d 115, 138 (2005) ("An opinion held to a reasonable degree of medical probability is sufficient."), *aff'd*, 391 Md. 608, 894 A.2d 563 (2006).

As to Biomet's first argument, defendants assert that Dr. Ebert "'formulated opinions going beyond what was necessary to provide appropriate care for the injured party [and] step[ped] into the shoes of a retained expert for purposes of Rule 26(a)(2).'" ECF 95-1 at 5 (quoting *Thomas v. Consol. Rail Corp.*, 169 F.R.D. 1, 2 (D. Mass. 1996)). According to defendants, Dr. Ebert did not formulate the opinion that the Magnum was the cause of plaintiff's revision surgeries during the course of his treatment of Dr. McCoy. Rather, he developed and articulated the opinion for the first time in response to this litigation, several years after performing surgery on plaintiff. ECF 95-1 at 5. Therefore, Biomet asserts that the opinion "exceeds the scope of treating physician testimony and is inadmissible without an expert report." *Id.* at 6.

Biomet principally relies on the reasoning of Judge Paul Grimm in *Sullivan v. Glock, Inc.*, 175 F.R.D. 497, 501 (D. Md. 1997).[9] That decision states, in pertinent part, *id.*:

> To the extent that the source of the facts which form the basis for a treating physician's opinions derive from information learned during the actual treatment of the patient—as opposed to being subsequently supplied by an attorney involved in litigating a case involving the condition or injury—then no Rule 26(a)(2)(B) statement should be required.

As Biomet notes, however, Fed. R. Civ. P. 37(c)(1) provides a limited exception to the requirement of Rule 26(a)(2)(B). Rule 37(c)(1) states (emphasis added):

> If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, *unless the failure was substantially justified or harmless*.

See Sullivan, 175 F.R.D. at 503-04 (discussing the rule); *see also Benjamin v. Sparks*, ___ F.3d ___, 2021 WL 161981, at *6 (4th Cir. Jan. 19, 2021) (addressing the "five factors that should

[9] In 1997, Judge Grimm was a U.S. magistrate judge. He is now a federal district judge in Maryland.

guide a district' court's analysis" of "substantial justification or harmlessness" under Rule 37(c)(1)).

Biomet also contends that Dr. Ebert's causation opinions are "based solely on his own-say-so," *i.e.*, ipse dixit, rather than on "any scientific knowledge." ECF 95-1 at 7. The gist of Biomet's argument is that Dr. Ebert's opinion lack both foundation and a reliable methodology. Even if Dr. Ebert's opinions survive challenge under Rule 26(a)(2)(B), or are subject to the Rule 37(c)(1) exception, they would nevertheless remain inadmissible under 702. Because I agree that the opinion concerning the defective design of the device is not reliable, I need not resolve the dispute regarding Rule 26. I turn to the issue of reliability under Rule 702 and *Daubert*.

Defendant emphasizes that at Dr. Ebert's deposition, he stated that the revision surgery he performed on Dr. McCoy in 2010 was his only experience with hip revision surgery involving the Magnum. *Id.* (citing ECF 95-3 at 17, Ebert Tr. 61-62). Moreover, defendants note that Dr. Ebert conceded that he has not conducted studies on "ingrowth of the Magnum" as compared to other hip implant devices. ECF 95-1 (citing ECF 95-3, Ebert Tr. 62). And, Dr. Ebert could not identify any medical or scientific publications that support his opinion regarding Dr. McCoy. ECF 95-1 (citing ECF 95-3, Ebert Tr. 62-63).

Plaintiffs counter that Dr. Ebert conducted a reliable differential diagnosis. They invoke the Fourth Circuit's statement that an admissible opinion of a medical expert regarding causation need not "'rule out every possible alternative cause of a plaintiff's illness.'" ECF 100 at 7 (quoting *Westberry*, 178 F.3d at 265). Plaintiffs cite Dr. Ebert's statements in his deposition testimony that elaborate on the opinion expressed in his affidavit.

In particular, plaintiffs note that Dr. Ebert expressly ruled out Rheumatoid arthritis as a cause of Dr. McCoy's revision surgeries. ECF 100 at 7-8 (citing ECF 95-3 at 7, Ebert Tr. 21).

Plaintiffs also highlight that Dr. Ebert testified that during his treatment of Dr. McCoy he found x-ray evidence of the loosening of her Magnum's acetabular cup. ECF 100 at 8 (citing ECF 95-3 at 10-11, Ebert Tr. 36-37). Further, Dr. Ebert testified that he ordered a pathology analysis of tissue samples (*i.e.*, cultures) taken from plaintiff's hip during her 2010 revision surgery, and that the analysis indicated that there was no bacterial growth in the cultures. ECF 100 at 8 (citing ECF 95-3 at 12, 14, Ebert Tr. 42-43, 49, 52). According to plaintiffs, the negative results as to bacterial growth support Dr. Ebert's conclusion that the purulence and debris found in plaintiff's hip were the results of an inflammatory response caused by the Magnum. ECF 100 at 8. Finally, plaintiffs characterize Dr. Ebert's treatment of Dr. McCoy as a sufficiently reliable methodology to support his opinions. ECF 100 at 9.

Multiple federal appellate courts have stated plainly that expert testimony from treating physicians is subject to the same admissibility requirements as the testimony of other expert witnesses. *See, e.g.*, *Musser v. Gentiva Health Servs.*, 356 F.3d 751, 757 (7th Cir. 2004) ("'[W]e do not distinguish the treating physician from other experts when the treating physician is offering expert testimony regarding causation.'") (citation omitted); *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1207 (8th Cir. 2000). Standing alone, Dr. Ebert's affidavit clearly fails to pass muster under Rule 702 and *Daubert*. It contains a single, conclusory sentence of analysis, which states that Dr. McCoy's 2010 revision surgery "was more likely than not necessary due to symptoms linked to" the MoM design of her Magnum implant. ECF 95-2. The affidavit does not address alternative causes of the revision surgery, let alone eliminate them, as required by *Westberry*, 178 F.3d at 262.

Dr. Ebert avers in his affidavit that he did not find evidence of infection during his examination of plaintiff on April 17, 2010, prior to the first revision surgery. The affidavit thus

alludes to the basis for eliminating infection as an alternative cause. But, the document does not "'provide a reasonable *explanation*,'" reflecting thorough attention and care to the details, as to why infection was not the sole cause of the revision surgery. *In re Lipitor*, 892 F.3d at 644 (citation omitted) (emphasis added). And, when pressed on the issue of infection at his deposition, Dr. Ebert failed clearly to rule it out as a cause of the revision surgery.

Defense counsel questioned Dr. Ebert about the medical records pertaining to Dr. McCoy's May 2010 revision surgery and the subsequent pathology report on tissue samples from her hip. The exchange established that during the surgery Dr. Ebert found and removed approximately forty to fifty milliliters of pus from plaintiff's hip joint, which Dr. Ebert thought might have been caused by an infection. ECF 95-3 at 11, Ebert Tr. 40. Dr. Ebert testified that after the surgery, he ordered a pathology report on tissue samples from plaintiff's hip. *Id.* at 43-44. Among other things, the pathology report found "granulation tissue," which Dr. Ebert defined as "inflammatory tissue" generated in response to "chronic irritation or inflammation," which might be caused by infection. *Id.* at 44.

To assess whether an infection was at play, Dr. Ebert had cultures taken of plaintiff's hip tissue and withdrew and tested additional purulent fluid. *Id.*at 49-50. Neither the cultures nor the tests on the aspirated fluid conducted under Dr. Ebert's supervision revealed evidence of bacterial growth. *Id.* at 50. However, defense counsel pressed Dr. Ebert on the probative value of bacterial cultures. He asked: "Is it possible that a patient can have an infection, even though operative cultures don't grow out any bacteria?" *Id.* at 50. Dr. Ebert responded: "Yes, it is possible." *Id.* Moreover, later in the deposition Dr. Ebert again conceded that "some aspects" of Dr. McCoy's "presentations . . . suggested that there was" an infection. *Id.* 54. Rather than eliminate infection as an alternative cause, Dr. Ebert opened the door to the possibility that a bacterial infection

contributed to the inflammation in and condition of Dr. McCoy's hip tissue. *See In re Lipitor*, 892 F.3d at 644; *Westberry*, 178 F.3d at 262. And, neither side has asserted that the Magnum could have caused the bacterial infection, if such infection existed, or identified evidence that would support such an assertion.

Dr. Ebert's explanation of the basis for his conclusion as to the Magnum's design fares no better. Defense counsel asked him, point blank: "Do you have an opinion as to why the acetabular component [of the Magnum implanted in Dr. McCoy] failed?" *Id.* 59. Dr. Ebert responded: "It didn't ingrow." *Id.* He then elaborated: "I think the metal-on-metal design -- the acetabular component is a poor design and it didn't ingrow." *Id.* at 60. The exchange established that the "sole basis" for this conclusion was Dr. Ebert's finding during the first revision surgery that he "found no bone ingrowth on the back of that cup." *Id.* As Biomet emphasizes, Dr. Ebert lacks clinical and research experience with the Biomet device. Moreover, he could not draw on any academic literature to support his conclusion. *Id.* at 62-63. His observation that plaintiff's Magnum did not ingrow, standing alone, does not rise to the level of reliable methodology under Rule 702. There is "simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146.

Accordingly, I shall grant the Ebert Motion, barring Dr. Ebert's proffered expert testimony as to the causation of plaintiff's revision surgeries and as to the alleged defective design of the Biomet device. However, my ruling does not bar Dr. Ebert from offering expert testimony as plaintiff's treating physician, consistent with ¶¶ 2, 3, and 4 of his affidavit (ECF 95-2).

C. The Shapiro Motion

Dr. Shapiro is a practicing, board-certified orthopedic surgeon. ECF 101-1 at 3; ECF 94-3 at 7, Shapiro Tr. 28. His practice is based at NYU Langone Orthopaedic Associates in New

York. ECF 101-1 at 3. He has appointments at four hospitals as well as an academic appointment. *Id.* His C.V. lists four publications on issues related to surgery and orthopedics. *Id.* at 5. His practice has, over time, focused on both hip surgery and knee surgery. ECF 94-3 at 7, Shapiro Tr. 28.

As of the time of Dr. Shapiro's deposition in February 2020, he was seeing patients with hip problems. *Id.* Dr. Shapiro has treated patients with MoM hip implants for approximately thirteen years. *Id.* at 29.

Dr. Shapiro's report is based on his review of the "[o]ffice notes" of Dr. Brassard; records from the Anne Arundel Medical Center, where Dr. Brassard practiced; the "[o]ffice notes" of Dr. Ebert; and Dr. Ebert's affidavit. ECF 94-2; *see* ECF 96-3 at 22-23. Dr. Shapiro summarized facts gleaned from his sources. ECF 94-2 at 3-5. His report set forth the following "Impression," *id.* at 5:

> "Adverse tissue" reaction to metal debris in a failed metal on metal prosthesis is documented clearly and classically in the records that I have reviewed on Joanna McCoy. She had a premature failure of her right total hip replacement. The classic findings on radiographs, as well as the findings at the timing of the operative procedures, are consistent with failure due to metal-on-metal breakdown, with adverse tissue reaction resulting in a failed hip replacement. There is no other explanation for the failure of her hip, such as implant malposition, trauma, infection, etc. It is my opinion, within a reasonable degree of medical certainty, that the destructive findings from the Biomet Magnum right total hip replacement inserted into Joanna McCoy are the result of the breakdown and failure of the metal-on-metal prosthesis in question (Biomet M2A total hip replacement). The multiple procedures that were performed were required as a result of the failure of that implant. There is no other explanation.

At his deposition, Dr. Shapiro was questioned by defense counsel as to his opinion. In addition, defense counsel asked Dr. Shapiro whether he would "be offering any testimony" as to plaintiffs' allegations that Biomet failed to warn Dr. McCoy about the risks associated with the Magnum. ECF 94-3 at 19, Shapiro Tr. at 76. Dr. Shapiro responded: "Well, based upon the report, I'm not giving an opinion. Okay? However, if

I'm asked, then I will give my opinion." *Id.* An exchange followed concerning the Magnum's IFU, described *supra*. *See id.* at 76-84.

Biomet seeks to exclude Dr. Shapiro's opinion as to causation as well as his opinion as to Biomet's alleged failure to warn. I address each argument, in turn.

1.

Biomet contends that Dr. Shapiro's causation opinion is unreliable for three main reasons. ECF 94-1 at 1. First, defendants argue that Dr. Shapiro did not review various materials that are critical to this case. In particular, Dr. Shapiro did not review radiographs taken of Dr. McCoy's right hip in 2008, after her total right hip replacement surgery, or the transcript from Dr. Ebert's deposition. *Id.* at 7. Second, defendants observe that, despite purporting to rely in part on Dr. Ebert's affidavit, Dr. Shapiro reached a different conclusion regarding the ingrowth of plaintiff's Magnum. And, according to Biomet, Dr. Shapiro's opinion as to ingrowth was riddled with other problems. *Id.* at 8. Third, Biomet asserts that Dr. Shapiro did not adequately rule out alternative causes of the failure of plaintiff's implant, and thus failed to produce a reliable differential diagnosis. *Id.*

As to the first of these three arguments, I do not share Biomet's view that, in essence, Dr. Shapiro's proffered testimony "is not based on sufficient facts or data." Rule 702(b). Biomet does not explain why the 2008 radiographs or the transcript of Dr. Ebert's deposition amount to smoking-gun-type evidence that would have compelled a different conclusion from Dr. Shapiro.

To be sure, the 2008 radiographs have probative value. The first images of plaintiff's hip that Dr. Shapiro personally reviewed date to April 17, 2010, by which point the acetabular cup in plaintiff's implant "was already loose." ECF 94-3 at 11, Shapiro Tr. 43. Images from 2008 are relevant to the question of when the acetabular cup began to loosen, which in turn is connected to

the task of determining the cause of the implant's failure. But, Dr. Shapiro relied on notes and records generated during Dr. Brassard's treatment of plaintiff between 2007 and 2010. ECF 94-2 at 2-3. As mentioned, Dr. Brassard's notes indicate that as of October 2008, nearly eleven months after plaintiff's hip replacement surgery, radiographs did not show any evidence of the loosening of the implant. *See* ECF 96-3 at 24. At trial, the defense may subject Dr. Shapiro to "[v]igorous cross-examination" as to the foundation for his opinion. *Daubert*, 509 U.S. at 596. But, at this juncture, the foundation for Dr. Shapiro's causation opinion is sufficient for purposes of admissibility.

That Dr. Shapiro did not review Dr. Ebert's deposition transcript does not alter the analysis. Nor does the fact that Dr. Shapiro relied in part on Dr. Ebert's affidavit, which I have excluded, as discussed, *supra*. Dr. Shapiro's opinion has a solid factual foundation for purposes of the *Daubert* inquiry. As plaintiffs put it, in the process of formulating his opinion Dr. Shapiro reviewed "six different sets of diagnostic imaging, and hundreds of pages of medical records from multiple treating physicians." ECF 101 at 3 (citing Dr. Shapiro's report, ECF 94-2).[10]

In addition, Dr. Shapiro testified that, prior to preparing his report, he also read the transcript of Dr. Brassard's deposition. ECF 94-3 at 4, Shapiro Tr. 14. And, before testifying, Dr. Shapiro spoke with Dr. McCoy for approximately one hour and reviewed the report produced by Dr. Bauer, one of the defense's expert witnesses, along with certain materials on which Dr. Bauer relied. ECF 94-3 at 3, 14, Shapiro Tr. 12, 56-57.

Therefore, Dr. Shapiro's opinions are based on sufficient facts or data, notwithstanding his consideration of Dr. Ebert's affidavit and his failure to review Dr. Ebert's deposition transcript.

[10] Although while Biomet takes issue with some of plaintiffs' factual assertions, it does not challenge this one.

Biomet also insists that Dr. Shapiro's opinion is unreliable because he concluded that plaintiff's implant experienced ingrowth, but "failed to determine what type of ingrowth occurred." ECF 105 at 3. At his deposition, Dr. Shapiro offered his view that Dr. McCoy's Magnum implant initially "gr[e]w in" to the adjoining bone through a combination of bone and "fibrous" connection. ECF 94-3 at 10, Shapiro Tr. 41. Then, according to Dr. Shapiro, "[a]t some point in time" Dr. McCoy experienced a "biologic response" and an "inflammatory response" to the metal of the Magnum. *Id.* Defense counsel repeatedly pressed Dr. Shapiro as to whether the ingrowth was "bony" or "fibrous," and whether one is stronger than the other. *See id.* at 46-47, 54, 60-61. In response, Dr. Shapiro maintained that there was ingrowth but that he could not specify the extent to which it was bony or fibrous. *See id.* at 46-47, 60-61. However, Dr. Shapiro also clearly asserted that ingrowth of a hip implant is not "an all-or-nothing phenomenon," contrary to defense counsel's characterization. *Id.* at 47. Moreover, he stated: "I don't believe that literature supports that all successful hip replacements have 100% ingrowth." *Id.* at 62.

Therefore, Biomet has not demonstrated that Dr. Shapiro's opinion is internally inconsistent or plagued by lacuna so great as to render his opinion inadmissible.

As noted, Biomet's third argument is that Dr. Shapiro has failed to eliminate alternative causes of Dr. McCoy's revision surgery, as required for a reliable differential diagnosis. In this regard, I am mindful of the Fourth Circuit's statement that while "'a reliable differential diagnosis need not rule out all possible alternative causes, it must at least consider other factors that could have been the sole cause of the plaintiff's injury.'" *In re Lipitor*, 892 F.3d at 644 (quoting *Guinn*, 602 F.3d at 1253). Moreover, the expert's burden is "'to provide a reasonable explanation as to . . . any alternative cause *suggested by the defense* . . . .'" *In re Lipitor*, 892 F.3d at 644 (citation omitted) (emphasis added).

Dr. Shapiro reasonably addressed and eliminated alternative causes suggested to him by the defense. On its face, Dr. Shapiro's report may seem conclusory. But, he was questioned repeatedly at his deposition about alternative causes. For instance, defense counsel asked him whether Dr. McCoy's "obesity impact[ed] her need for revision?" ECF 94-3 at 7, Shapiro Tr. 26. Dr. Shapiro replied: "I believe it is not directly related to the failure." There were no follow-up questions. *Id.* A similar exchange occurred regarding the possibility that the revision surgery "was due to infection." *Id.* at 65. Defense counsel also asked Dr. Shapiro about the impact of Dr. McCoy's fall on her Magnum implant. Dr. Shapiro responded that, based on his review of the relevant medical records from the time, there was "no impact from the fall" on the fixation of the Magnum. *Id.* at 60. Again, defense counsel did not press the matter further.

Biomet asserts that Dr. Shapiro failed to rule out Dr. McCoy's medical history and other health conditions as factors in the failure of her Magnum implant. ECF 105 at 4. Defendant highlights that when Dr. Shapiro was asked whether he had "assess[ed] Dr. McCoy's past medical history and co-morbidities," he answered that he had not. ECF 94-3 at 14, Shapiro Tr. 54. However, defense counsel did not ask any follow-up questions about whether any particular co-morbidities or elements of plaintiff's medical history could have factored into the need for revision surgery. Likewise, Dr. Shapiro was not questioned about whether the reports produced by any of Biomet's expert witnesses challenged or contradicted his own opinions. Defense counsel had ample opportunity to present Dr. Shapiro with competing facts or data with which to question him at his deposition. Under the circumstances here, Dr. Shapiro has provided reasonable explanations to possible alternative causes "suggested by the defense . . . ." *In re Lipitor*, 892 F.3d at 644 (citation omitted).

2.

As indicated, in his report Dr. Shapiro did not opine as to Biomet's warnings regarding the Magnum. But, at his deposition, Dr. Shapiro was questioned about Biomet's warnings, and specifically about the IFU. *See* ECF 94-3 at 19-21, Shapiro Tr. 76-83.

Defense counsel asked Dr. Shapiro why he did not opine on warnings in his report. *Id.* at 76. In addition, defense counsel observed that, in other cases in which Dr. Shapiro offered opinions as an expert witness, he had addressed warning claims. *Id.* Dr. Shapiro answered: "There is nothing in this specific case that brought up the issue of failure to warn the surgeon or failure to let the patient know, but there are issues out there." *Id.*

Significantly, defense counsel asked: "Generally, not specific to Dr. McCoy, what are your opinions regarding the sufficiency of the IFU . . . to identify adverse effects associated with the [Magnum]?" *Id.* at 80. Dr. Shapiro prefaced his response by stating that "the overwhelming majority of surgeons . . . never read" documents like the IFU prior to performing surgery. *Id.* According to Dr. Shapiro, packaging inserts like the IFU are "not where we get our knowledge from." *Id.*

Dr. Shapiro proceeded to address the content of the IFU. He asserted "that the majority of surgeons, if they were to read [the IFU], would focus on" the section titled "Warnings," rather than the section titled "Possible Adverse Effects." *Id.* at 81. He then addressed the tenth possible adverse effect listed in the IFU, which states: "Fretting and crevice corrosion may occur at interfaces between components." ECF 96-6. Dr. Shapiro opined that "if this issue of these implants had been placed under warnings," rather than Possible Adverse Effects, "[i]t may have drawn more attention to those who would have read it, even though, in my opinion, most surgeons do not or have not read this." ECF 94-3 at 21, Shapiro Tr. 82.

Dr. Shapiro was asked whether there is "anything materially false" in the IFU, and he answered: "Not that I'm aware of." *Id.* He was not asked about any other component of the IFU, nor did he specifically address any other component.

Biomet seeks to exclude Dr. Shapiro's opinion about the IFU on the grounds that Dr. Shapiro is not qualified to offer it and failed to employ a reliable methodology. *See* ECF 94-1 at 10-12. As to qualifications, Biomet asserts that Dr. Shapiro "has no regulatory expertise and does not consider himself to be an expert in FDA regulations that apply to orthopedic medical devices." *Id.* at 11 (citing ECF 94-3 at 18, Shapiro Tr. 70). As to reliability, defendants contend that Dr. Shapiro's opinion is directed to the IFU's "formatting" rather than its substance. ECF 94-1 at 11. Moreover, in defendants' view Dr. Shapiro's assertion that most surgeons do not read documents like the IFU undermines whatever opinion he has about the IFU's deficiencies. *Id.*

Plaintiffs maintain that Dr. Shapiro is qualified to opine about the IFU. ECF 101 at 4-5. And, they contend that Dr. Shapiro's conclusion is similar to that of Ms. Truman and Dr. Kantor, the MDL plaintiffs' general causation experts, which "underscor[es] the reliability of [Dr. Shapiro's] opinion based on his medical training and experience." *Id.* at 5.

Both Biomet and plaintiffs rely on *Hardison v. Biomet, Inc.*, 5:19-CV-00069-TES, 2020 WL 4334108 (M.D. Ga. July 27, 2020), which was part of the same MDL as this case and also involved Dr. Shapiro's proffered expert testimony. There, plaintiffs offered the following opinion evidence from Dr. Shapiro, *id.* at 5:

> Dr. Shapiro seeks to opine that Biomet's IFU and marketing activities failed to provide proper warnings of the risks associated with the M2a Magnum and the resulting generation of metal debris. . . . Further, Dr. Shapiro stated that "[h]ad Mr. Hardison and his implanting surgeon been aware of the true risks associated with Biomet's product, they likely would have selected a safer alternative implant."

In *Hardison*, Biomet moved to exclude Dr. Shapiro's failure-to-warn opinion under Rule 702. *Hardison* does not describe the basis for Dr. Shapiro's failure-to-warn opinions. Nor does *Hardison* indicate whether Dr. Shapiro was questioned about these opinions at a deposition.

The court concluded that Dr. Shapiro was not qualified to opine on "the communication of the warnings" through the IFU. *Id.* at 6. However, the court also ruled that Dr. Shapiro was "qualified to testify as to how a surgeon would react to a properly-communicated warning and whether that would affect a surgeon's willingness to use the device." *Id.*

In light of the opinion evidence presented in this case, I am of the view that plaintiffs have not established the admissibility of Dr. Shapiro's failure-to-warn opinion. Plaintiffs appear to seek a ruling similar to that of *Hardison*, namely, that Dr. Shapiro, as an experienced orthopedic surgeon, is qualified to opine as to how an orthopedic surgeon would use or respond to the content of the IFU. Yet, Dr. Shapiro testified, on the basis his experience, that most surgeons do not read documents like the IFU. Thus, it is unclear what aspect of Dr. Shapiro's experience plaintiffs believe qualifies him to opine about how the content of the IFU might have affected the behavior of Dr. Brassard in this case, or more generally, of orthopedic surgeons working with the Magnum. *See Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001) (determining that board-certified orthopedic surgeon with no experience drafting instructional documents or warnings for medical devices was not qualified to opine on the adequacy of a warning, reasoning that such a warning would stray beyond the "reasonable confines" of the expert's "subject area"); *Avila v. Willits Envtl. Remediation Tr.*, 633 F.3d 828, 839 (9th Cir. 2011) (affirming the exclusion of proffered testimony and relying on *Ralston*).

Moreover, Dr. Shapiro's opinion, as expressed in his deposition testimony, is conclusory. He asserts that one of the cautionary statements listed in the IFU under "Possible Adverse Effects"

might "have may have drawn more attention to those who would have read it" if it were listed under "Warnings." ECF 94-3 at 20, Shapiro Tr. 82. But, no explanation or basis was provided for this opinion. And, I agree with Biomet that Dr. Shapiro's testimony that most surgeons would not have read the IFU undermines his barebones opinion about the IFU's deficiency. In short, Dr. Shapiro's failure-to-warn opinion is merely ipse dixit. Therefore, it is inadmissible. *See Joiner*, 522 U.S. at 146; *see also Oglesby*, 190 F.3d at 250 (stating that expert testimony based on "belief or speculation" is inadmissible); *In re Zimmer Nexgen Knee Implant Prod. Liab. Litig.*, No. 11 C 5468, 2015 WL 3669933, at *32 (N.D. Ill. June 12, 2015) ("'[A]n expert who supplies nothing but a bottom line supplies nothing of value to the judicial process.'") (quoting *Wendler & Ezra, P.C. v. Am. Int'l Grp., Inc.*, 521 F.3d 790, 791 (7th Cir. 2008)). Accordingly, I shall grant Biomet's Shapiro Motion as to Dr. Shapiro's failure-to-warn testimony.

III. Summary Judgment Motions

A. Legal Standard

Under Rule 56(a) of the Federal Rules of Civil Procedure, summary judgment is appropriate only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322-24 (1986); *see also Cybernet, LLC v. David*, 954 F.3d 162, 168 (4th Cir. 2020); *Variety Stores, Inc. Wal-Mart Stores, Inc.*, 888 F.3d 651, 659 (4th Cir. 2018); *Iraq Middle Mkt. Dev. Found v. Harmoosh*, 848 F.3d 235, 238 (4th Cir. 2017). To avoid summary judgment, the nonmoving party must demonstrate that there is a genuine dispute of material fact so as to preclude the award of summary judgment as a matter of law. *Ricci v. DeStefano*, 557 U.S. 557, 585-86 (2009); *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986); *see also Gordon v. CIGNA Corp.*, 890 F.3d 463, 470 (4th Cir. 2018).

The Supreme Court has clarified that not every factual dispute will defeat a summary judgment motion. "By its very terms, this standard provides that the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original). A fact is "material" if it "might affect the outcome of the suit under the governing law." *Id.* at 248.

There is a genuine issue as to material fact "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*; *see CTB, Inc. v. Hog Slat, Inc.*, 954 F.3d 647, 658 (4th Cir. 2020); *Variety Stores, Inc.*, 888 F.3d at 659; *Sharif v. United Airlines, Inc.*, 841 F.3d 199, 2014 (4th Cir. 2016); *Libertarian Party of Va. v. Judd*, 718 F.3d 308, 313 (4th Cir. 2013). On the other hand, summary judgment is appropriate if the evidence "is so one-sided that one party must prevail as a matter of law." *Anderson*, 477 U.S. at 252. But, "the mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." *Id.*

"A party opposing a properly supported motion for summary judgment 'may not rest upon the mere allegations or denials of [its] pleadings,' but rather must 'set forth specific facts showing that there is a genuine issue for trial.'" *Bouchat v. Balt. Ravens Football Club, Inc.*, 346 F.3d 514, 522 (4th Cir. 2003) (quoting former Fed. R. Civ. P. 56(e)), *cert. denied*, 541 U.S. 1042 (2004); *see Celotex*, 477 U.S. at 322-24. And, the court must view all of the facts, including reasonable inferences to be drawn from them, in the light most favorable to the nonmoving party. *Ricci*, 557 U.S. at 585-86; *Matsushita Elec. Indus. Co.*, 475 U.S. at 587; *accord Hannah P. v. Coats*, 916 F.3d 327, 336 (4th Cir. 2019); *Variety Stores, Inc.*, 888 F.3d at 659; *Gordon*, 890 F.3d at 470; *Lee v.*

Town of Seaboard, 863 F.3d 323, 327 (4th Cir. 2017); *FDIC v. Cashion*, 720 F.3d 169, 173 (4th Cir. 2013).

The district court's "function" is not "to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249; *accord Guessous v. Fairview Prop. Invs., LLC*, 828 F.3d 208, 216 (4th Cir. 2016). Thus, in considering a summary judgment motion, the court may not make credibility determinations. *Wilson v. Prince George's Cty.*, 893 F.3d 213, 218-19 (4th Cir. 2018); *Jacobs v. N.C. Administrative Office of the Courts*, 780 F.3d 562, 569 (4th Cir. 2015); *Mercantile Peninsula Bank v. French*, 499 F.3d 345, 352 (4th Cir. 2007). Therefore, in the face of conflicting evidence, such as competing affidavits, summary judgment ordinarily is not appropriate, because it is the function of the fact-finder to resolve factual disputes, including matters of witness credibility. *See Black & Decker Corp. v. United States*, 436 F.3d 431, 442 (4th Cir. 2006); *Dennis v. Columbia Colleton Med. Ctr., Inc.*, 290 F.3d 639, 644-45 (4th Cir. 2002). That said, "a party's 'self-serving opinion ... cannot, absent objective corroboration, defeat summary judgment.'" *CTB, Inc.*, 954 F.3d at 658-59 (quoting *Williams v. Giant Food Inc.*, 370 F.3d 423, 433 (4th Cir. 2004)). In other words, "[u]nsupported speculation is not sufficient to defeat a summary judgment motion." *Felty v. Graves-Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987); *Harris v. Home Sales Co.*, 499 F. App'x 285, 294 (4th Cir. 2012).

When, as here, the parties have filed cross-motions for summary judgment, the court "'consider[s] each motion separately on its own merits to determine whether either of the parties deserves judgment as a matter of law.'" *Def. of Wildlife v. N.C. Dep't of Transp.*, 762 F.3d 374, 392 (4th Cir. 2014) (citation omitted). In doing so, the court "'resolve[s] all factual disputes and any competing, rational inferences in the light most favorable to the party opposing that motion.'"

Id. at 393 (quoting *Rossignol v. Voorhaar*, 316 F.3d 516, 523 (4th Cir. 2003), *cert. denied*, 540 U.S. 822 (2003)); *see Mellen v. Bunting*, 327 F.3d 355, 363 (4th Cir. 2003).

Simply because both parties have filed for summary judgment does not mean that summary judgment to one party or another is necessarily appropriate. Rather, "[b]oth motions must be denied if the court finds that there is a genuine issue of material fact." 10A C. WRIGHT, A. MILLER, & M. KANE, FEDERAL PRACTICE & PROCEDURE § 2720 (4th ed. Suppl. 2020) (WRIGHT & MILLER).

B. Biomet's Summary Judgment Motion

1. Strict Liability (Count 1) & Negligence (Count 2)

a.

As noted, in Count I plaintiffs allege strict product liability under Maryland law. Count II lodges a claim for negligence under Maryland law. In a product liability case, "'the elements of proof are the same whether the claim [is] characterized as one for strict liability or negligence[.]'" *Heckman v. Ryder Truck Rental, Inc.*, 962 F. Supp. 2d 792, 802 (D. Md. 2013) (quoting *Shreve*, 166 F. Supp. 2d at 407).

"A product defect may arise from the design of the product, a deficiency in its manufacture, or from the absence or inadequacy of instructions or warnings as to its safe and appropriate use." *Shreve*, 166 F. Supp. 2d at 407 (citing *Simpson v. Standard Container Co.*, 72 Md. App. 199, 203, 527 A.2d 1337, 1339–40 (1987)); *see Phipps v. Gen Motors Corp.*, 278 Md. 337, 345, 363 A.2d 955, 960 (Md. 1976); *Kelley v. R.G. Indus., Inc.*, 304 Md. 124, 135, 497 A.2d 1143, 1148 (1985); *Owens–Illinois, Inc. v. Zenobia*, 325 Md. 420, 601 A.2d 633, 639 (1992). In *Nissan Motor Co. v. Nave*, 129 Md. App. 90, 118, 740 A.2d 102, 117 (1999), the Maryland Court of Special Appeals explained (citations omitted):

> There are three situations in which a product is in a "defective condition": (1) there is a flaw in the product at the time of sale making it more dangerous than intended;

> (2) the manufacturer of the product fails to warn adequately of a risk or hazard related to the way the product was designed; or (3) the product has a defective design.

Plaintiffs' strict product liability and negligence claims are based on each of the three theories identified in the case law: manufacturing defect, design defect, and failure to warn. Biomet contends that plaintiffs' "negligence claim fails as a matter of law" to the extent that it is based on any theory other than "negligent design, manufacture, and failure to warn." ECF 96-1 at 37. In particular, defendants take issue with the allegation in plaintiffs' Amended Complaint that defendants "negligently failed to exercise ordinary care in the design, manufacture, testing, inspection, labeling, promotion, marketing, and sale of the" Magnum. ECF 43, ¶ 112. In their opposition, plaintiffs counter that the negligence claim "is adequate because it contains the necessary elements for product defect and failure to warn." Thus, both sides appear to agree that the negligence claim is premised on theories of design defect and failure to warn. I construe the Amended Complaint, including ¶ 112, accordingly.

In their opposition to Biomet's Summary Judgment Motion, plaintiffs consent to the dismissal of Count I as to manufacturing defects. ECF 103 at 2. Thus, plaintiffs' theories of defective design and failure to warn remain.

b.

Biomet argues that Count I and Count II must be dismissed because plaintiffs have failed to identify any triable issues as to "medical causation" with respect to Dr. McCoy's hip revision surgeries. ECF 96-1 at 18-19. First, Biomet reiterates its position that the opinion evidence of Dr. Shapiro and Dr. Ebert is inadmissible. *Id.* at 20-23. Next, defendants assert that the opinion evidence from its three expert witnesses "affirmatively establishes that Dr. McCoy's need for revision surgery was related to biomechanical, clinical, and patient factors, not the . . . Magnum

device itself." *Id.* at 23-24. According to defendants, the opinions from its three expert witnesses compel the following findings, *id.* at 26-27:

> Dr. McCoy's M2a Magnum cup was implanted in a suboptimal position and had a less tight fit into her acetabulum due to line-to-line reaming, which resulted in the Magnum cup's loosening and migration and her need for revision surgery. Various patient factors and a periprosthetic infection also likely impacted the functioning of Dr. McCoy's right hip implant and her need for revision surgery. Put simply, a combination of biomechanical, clinical, and patient factors caused Dr. McCoy's need for revision surgery, not any alleged defect in the M2a Magnum.

And, defendants contend: "Even if Dr. Ebert and Dr. Shapiro's case-specific opinions were admissible, all of Plaintiffs' claims still fail because their testimony does not link a specific product defect to Dr. McCoy's claimed injuries." *Id.* at 27. In other words, defendants' view is that plaintiffs have failed to present any genuine issues of material fact as to causation, and that defendants are, accordingly, entitled to judgment as a matter of law with respect to Counts I and II. *Id.* at 27, 35.

Proximate cause is a necessary element in actions for negligence and strict liability. *Ford Motor Co. v. Gen. Accident Ins. Co.*, 365 Md. 321, 335, 779 A.2d 362, 369–70 (2001) (identifying the three "product litigation basics" as defect, attribution of defect to seller, and a causal relationship between the defect and the injury) (citing *Harrison v. Bill Cairns Pontiac*, 77 Md. App. 41, 50, 549 A.2d 385, 390 (1988)); *Arbogast v. A.W. Chesterton Co.*, 197 F. Supp. 3d 807, 811 (D. Md. 2016); *see Pittway Corp. v. Collins*, 409 Md. 218, 255 n.17, 973 A.2d 771, 793 n.17 (2009) (noting that proximate cause is a necessary element of product liability claims based on theories of both strict liability and negligence). A defendant's conduct is the proximate cause of a plaintiff's injury when it is "1) a cause in fact, and 2) a legally cognizable cause." *Pittway*, 409 Md. at 243, 973 A.2d at 786; *see Copsey v. Park*, 453 Md. 141, 164, 160 A.3d 623, 636 (2017).

The Maryland Court of Appeals has explained, *Pittway*, 409 Md. at 243–44, 973 A.2d at 786:

> In other words, before liability may be imposed upon an actor, we require a certain relationship between the defendant's conduct and the plaintiff's injuries. The first step in the analysis to define that relationship is an examination of causation-in-fact to determine who or what caused an action. The second step is a legal analysis to determine who should pay for the harmful consequences of such an action.

The causation-in-fact inquiry asks "'whether defendant's conduct actually produced an injury.'" *Id.* at 244, 973 A.2d at 786 (quoting *Peterson v. Underwood*, 258 Md. 9, 16–17, 264 A.2d 851, 855 (1970)). Maryland courts have developed two tests to determine whether the requisite causation exists: the "but-for test" and the "substantial factor" test. *Pittway*, 409 Md. at 244, 973 A.2d at 786. [11]

Under the but-for test, the requisite causation exists when the injury would not have occurred but for the defendant's conduct. *Pittway*, 409 Md. at 244, 973 A.2d at 786–87 (citing *Peterson*, 258 Md. at 16, 264 A.2d at 855). The but for test applies in cases where only one negligent act is at issue. *Id.* at 244, 973 A.2d at 786.

The Maryland Court of Appeals has also adopted the substantial factor set forth in the Restatement (Second) of Torts (1965). *Pittway*, 409 Md. at 244, 973 A.2d at 787 (citing *Eagle-Picher Indus., Inc. v. Balbos*, 326 Md. 179, 208–09, 604 A.2d 445, 459 (1992)). Under the substantial factor test, the requisite causation may be found if it is "'more likely than not'" that the defendant's conduct was a substantial factor in producing the plaintiff's injuries. *Copsey*, 453 Md. at 164, 160 A.3d at 636 (quoting *Pittway*, 409 Md. at 244, 973 A.2d at 787); *accord Balbos*, 326 Md. at 209, 604 A.2d at 459. This test applies when two or more independent acts bring about an injury. *Pittway*, 409 Md. at 244, 973 A.2d at 787.

[11] Neither side has addressed whether Dr. Shapiro's opinion evidence establishes causation-in-fact under either the but-for test or the substantial factor test, as articulated in Maryland case law.

In determining whether the requisite connection exists under the substantial factor test, the following considerations are relevant:

> (a) the number of other factors which contribute in producing the harm and the extent of the effect which they have in producing it;
>
> (b) whether the actor's conduct has created a force or series of forces which are in continuous and active operation up to the time of the harm, or has created a situation harmless unless acted upon by other forces of which the actor is not responsible;
>
> (c) lapse of time.

Pittway, 409 Md. at 245, 973 A.2d at 787 (quoting Restatement, § 433).

If causation in fact is established under the appropriate test, the proximate cause analysis turns to whether the defendant's conduct was the legal cause of the plaintiff's injuries. *Copsey*, 453 Md. at 165, 160 A.3d at 637; *Pittway*, 409 Md. at 245, 973 A.2d at 787. This analysis focuses on foreseeability; the court asks whether the "actual harm to a litigant falls within a general field of danger that the actor should have anticipated or expected." *Pittway*, 409 Md. at 245, 973 A.2d at 787.[12]

Moreover, to establish causation in product liability cases, the plaintiff must "link the defendant to the product." *Scapa Dryer Fabrics, Inc. v. Saville*, 418 Md. 496, 510, 16 A.3d 159, 167 (2011); *see Reiter v. Pneumo Abex, LLC*, 417 Md. 57, 69, 8 A.3d 725, 732 (2010); *see also Lohrmann v. Pittsburgh Corning Corp.*, 782 F.2d 1156, 1162–63 (4th Cir. 1986) ("To support a reasonable inference of substantial causation from circumstantial evidence, there must be evidence of exposure to a specific product on a regular basis over some extended period of time in proximity to where the plaintiff actually worked."); *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 93 (D.

[12] The defense of superseding cause "arises primarily when 'unusual' and 'extraordinary' independent intervening acts occur that could not have been anticipated by the original tortfeasor.'" *Pittway*, 409 Md. at 249, 973 A.2d at 789 (citation omitted).

Md. 1989) ("Maryland courts apply traditional products liability law which requires the plaintiff to prove that the defendant manufactured the product which allegedly caused the injury."); W. Page Keeton, *Prosser & Keeton on the Law of Torts* § 103 at 713 (5th ed. 1984) ("It is quite clear that an essential element of the plaintiff's case has been the identification of the named defendant as the manufacturer or supplier of the defective product.").

Biomet contends that Dr. Shapiro's opinion evidence as to the Magnum's defective design does not raise a genuine issue of material fact. But, Biomet's argument merely rehashes its position that this opinion of Dr. Shapiro is inadmissible. To illustrate, Biomet concludes the pertinent section in its Summary Judgment Motion by asserting: "Dr. Shapiro's opinion, based on incomplete analysis of possible alternative reasons for Dr. McCoy's hip failure, combined with his disregard of Dr. Ebert's operative findings and subsequent testimony does not provide proof of a link between a specific product defect and Dr. McCoy's injuries." ECF 96-1 at 31.

As discussed, I have already explained why Dr. Shapiro's opinion as to the Magnum's defective design was based on a sufficient foundation for purposes of Rule 702, despite the fact that he did not independently review certain images of Dr. McCoy's hip and he reached certain subsidiary conclusions that conflicted with those of Dr. Ebert, whose proffered testimony I have excluded as to design defect. And, I determined that Dr. Shapiro's report and deposition testimony, taken together, adequately explained his reasons for eliminating alternative causes suggested by the defense. Thus, his differential diagnosis is admissible. Whatever criticisms Biomet lodges against this evidence at this stage goes to weight, which is the province of the jury, and not to admissibility. *See Anderson*, 477 U.S. at 249; *Guessous*, 828 F.3d at 216 (4th Cir. 2016).

Dr. Shapiro's opinion evidence as to a design defect establishes a genuine issue of material fact as to whether the Magnum's design caused harm to plaintiff, which is pertinent to both Count

I and Count II. There is no question that the evidence from both sides linked Biomet to the Magnum implant at issue in this case. Further, through Dr. Shapiro's opinion evidence, plaintiffs have presented evidence that the Magnum's MoM design caused a breakdown of metal that, in turn, adversely affected the surrounding tissue and resulted in the Magnum's premature failure, requiring hip revision surgeries. According to Dr. Shapiro, "[t]here is no other explanation." ECF 94-2 at 5. Thus, Dr. Shapiro's opinion serves as evidence from which a jury could find that the "breakdown and failure" of the Magnum's MoM design was the cause-in-fact of Dr. McCoy's revision surgeries. *See Pittway*, 409 Md. at 244, 973 A.2d at 786–87.

Moreover, the report of Ms. Truman, one of the MDL plaintiffs' general-causation experts, establishes a factual basis on which a court could conclude that the failure of Dr. McCoy's Biomet implant was foreseeable and, thus, the proximate cause of her revision surgeries. In her report, Ms. Truman found: "Biomet MoM hip systems are unreasonably dangerous and defective in design and present an unreasonable risk of harm to patients." ECF 103-6 at 86. Of relevance here, Ms. Truman opined that one particular defect of the Magnum's MoM design "was well known to Biomet before it marketed" the device. *Id.* As to defendants' testing of the Magnum, her report states that it "was deficient, and was a substantial factor in the harms experienced by its MoM patients." *Id.* at 87. In particular, she asserts that Biomet "failed to quantify the probability of occurrence of . . . excessive wear scenarios." *Id.* In addition, Ms. Truman concluded that Biomet knew of but "continuously downplayed the serious and unreasonable danger associated with its MoM hip implant devices . . . compared to safer alternative devices" with an MoP design. *Id.* at 89. Taking the respective reports of Dr. Shapiro and Ms. Truman together, plaintiffs have presented evidence from which a jury could reasonably find that the Magnum design was the proximate cause of plaintiff's injuries.

At trial, Biomet is entitled to mount a vigorous defense in an effort to contest the strength and credibility of the testimony of Dr. Shapiro and Ms. Truman, as well as that of plaintiffs' other general-causation witnesses. Indeed, it may use the opinion evidence regarding causation generated by its three experts to great effect. At this stage, I conclude only that on this summary judgment record, viewed in the light most favorable to plaintiffs, they have presented questions about causation that are properly for the jury to resolve. *See Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 562 (8th Cir. 2014) ("[D]istrict courts are admonished not to weigh or assess the correctness of competing expert opinions."); *Moreland*, 437 F. 3d at 431; *see also Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 433 (7th Cir. 2013) ("Rule 702 did not require, or even permit, the district court to choose between . . . two studies at the gatekeeping stage. Both experts were entitled to present their views, and the merits and demerits of each study can be explored at trial.")

c.

I turn to plaintiffs' claims for strict product liability and negligence under a theory of failure to warn.

A seller has a duty to warn of the dangers of a product "'if the item produced has an inherent and hidden danger that the producer knows or should know could be a substantial factor in causing an injury.'" *Shreve*, 166 F. Supp. 2d at 413 (quoting *Virgil v. Kash N' Karry Serv. Corp.*, 61 Md. App. 23, 484 A.2d 652, 657 (1984)); *see Zenobia*, 325 Md. at 437, 601 A.2d at 641 (holding that a seller "is not strictly liable for failure to warn unless the seller has 'knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ... danger' ") (quoting Restatement, § 402A cmt. j); *see also May v. Air & Liquid Systems Corp.*, 446 Md. 1, 9, 129 A.3d 984, 988 (2015); *Georgia Pac., LLC v. Farrar*, 432 Md.

523, 530–31, 69 A.3d 1028, 1033 (2013); *Moran v. Faberge, Inc.*, 273 Md. 538, 544–45, 332 A.2d 11, 15–16 (1975). Conversely, a seller does not have a duty to warn of an open and obvious danger in its product. *Mazda Motor of Am., Inc. v. Rogowski*, 105 Md. App. 318, 326, 659 A.2d 391, 395 (1995); *Virgil*, 61 Md. App. at 33, 484 A.2d at 657.

"'Whether there is a duty to warn and the adequacy of warnings given must be evaluated in connection with the knowledge and expertise of those who may reasonably be expected to use or otherwise come into contact with the product . . . .'" *Emory v. McDonnell Douglas Corp.*, 148 F.3d 347, 350 (4th Cir. 1998) (quoting *Mazda Motor*, 105 Md. App. at 327, 659 A.2d at 395). Notably, to be legally adequate, a "'warning must only be reasonable, not the best possible one.'" *Morris*, 2020 WL 5849482, at *9 (quoting *Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 572 (D. Md. 2006)). In other words, under Maryland law, a reasonable warning need not be "'an encyclopedic warning.'" *Morris*, 2020 WL 5849482, at *9 (quoting *Hartford Mut. Ins. Co. v. Apria Healthcare, Inc.*, 159 F. App'x 479, 483 (4th Cir. 2005)). Moreover, as with a claim of strict product liability on the basis of a design defect theory, plaintiffs' strict product liability claim on the basis of a failure to warn requires proof of causation. *See Arbogast*, 197 F. Supp. 3d at 811; *Pittway*, 409 Md. at 255 n.17, 973 at 793 n.17; *Ford Motor Co.*, 365 Md. at 335, 779 A.2d at 369–70.

Courts in Maryland apply the learned intermediary doctrine to failure-to-warn claims involving medical devices. "Under the learned intermediary doctrine, the manufacturer of medical devices . . . has no duty to warn the patient of the risks associated with products used under the supervision of a doctor. . . . The manufacturer's duty to warn is limited to adequately informing the patients' doctor of any risks associated with the product's use." *Miller v. Bristol-Myers Squibb Co.*, 121 F. Supp. 2d 831, 838 (D. Md. 2000) (citing *Doe v. Miles Laboratories, Inc.*, 927 F.2d

187, 194 (4th Cir.1991); *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 94–95 (D.Md.1989), *aff'd*, 898 F.2d 146 (4th Cir.1990); *Fellows v. USV Pharmaceutical Corp.*, 502 F. Supp. 297 (D.Md.1980)); *see Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 568 (D. Md. 2006) ("The doctrine's essence is that if the prescribing doctor (the learned intermediary) has received adequate notice of a drug's risks the manufacturer has no duty to warn the consumer.").

At Ms. Truman's deposition (ECF 103-8), she opined that some of the "Possible Adverse Effects" listed in the IFU either understated the probability or magnitude of certain effects, including local tissue reactions, *id.* at 283, or were "somewhat misleading" or poorly worded as to others. *Id.* at 285; *see id.* at 287. Moreover, Ms. Truman found in her report: "Biomet's failure to calculate and communicate the *probability* of the new risks of MoM articulations to surgeons . . . prevented them from making informed product selections, and deprived them of the ability to choose safer alternative devices." ECF 103-6 at 88 (emphasis added).

Here, the proper focus of the learned intermediary doctrine is on the duty to warn owed by Biomet to Dr. Brassard, the surgeon who implanted the Magnum in Dr. McCoy as part of her hip replacement surgery in 2007. In essence, Biomet contends that the failure-to-warn claims lack merit for two main reasons: the warnings provided to Dr. Brassard "are adequate under Maryland law," and plaintiffs have not presented evidence that the warnings caused plaintiff harm. ECF 96-1 at 34-35.

As to the first of those reasons, Biomet's argument boils down to the following assertion: "Plaintiffs' warning claims fail because it is undisputed that the IFU warns of the very complications that Plaintiffs claim Dr. McCoy experienced with her hip implant — adverse tissue reaction and cup loosening." *Id.* at 35; *see also* ECF 106 at 8-9. In other cases that were part of this MDL class, Biomet has mounted similar defenses to failure-to-warn claims, contending that

such a claim cannot be actionable where a plaintiff experienced effects addressed in the Magnum's IFU.

Courts have reached different conclusions as to this defense. For instance, in *Morris*, 2020 WL 5849482, at *10 n.6, Judge Hazel reasoned:

> The Court is not prepared to conclude that Biomet's warnings were adequate as a matter of law, particularly with respect to the magnitude of the risks associated with metallosis and pseudotumors. *See In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 773 (5th Cir. 2018) (denying summary judgment to defendant where "the warning fail[ed] to put surgeons on notice as to the distinctive risks that arise from [metal-on-metal devices]—'metallosis,' 'pseudotumors,' and 'tissue necrosis'—*or the magnitude of those risks.*" (emphasis added)).

In contrast, in *Nicholson*, 2020 WL 3399899, at *15, the court concluded, on the basis of Iowa law (alterations added):

> [The IFU] provide[s] a reasonable warning of a foreseeable result that has occurred in some patients who received the . . . Magnum. Thus, because the IFUs provided information about the harm that allegedly occurred, the Court finds the warnings were adequate.

I am persuaded by Judge Hazel's reasoning as to the adequacy of the warnings. As noted, Ms. Truman opined that the IFU understated the probability or magnitude of the Magnum's adverse effects, and that Biomet failed to communicate to surgeons the probability of risks associated with the Magnum's MoM design. Under the case law cited by Judge Hazel, evidence that a manufacturer failed to inform surgeons of the magnitude of risks associated with a medical device may create a genuine dispute of material fact as to a failure-to-warn claim. *See* 2020 WL 5849482, at *10 n.6. Here, Ms. Truman's opinion evidence precludes summary judgment on plaintiffs' failure-to-warn claims.

Moreover, "[t]here is a presumption in strict liability cases that a plaintiff would have read and heeded an adequate warning if it had been given." *Waterhouse v. R.J. Reynolds Tobacco Co.*, 162 F. App'x 231, 234 (4th Cir. 2006) (per curiam). The question is whether Dr. Brassard, as the

learned intermediary, would have acted differently had he received an adequate warning. To establish causation-in-fact, plaintiffs must prove not only that Dr. Brassard "'would have read, understood, and remembered the warning, but also that [he] would have altered [his] conduct to avoid the injury.'" *Id.* (quoting *Balbos*, 326 Md. at 227, 604 A.2d at 468) (brackets in *Waterhouse*). "The presumption may be rebutted where there is 'evidence that the personalities or dispositions of the [plaintiffs] were such that they clearly would have ignored warnings.'" *Id.* (quoting *Balbos*, 326 Md. at 227, 604 A.2d at 468).

At this juncture, defendants have not identified evidence sufficient to rebut the presumption that Dr. Brassard would have heeded an adequate warning or changed his recommendation or course of conduct. To be sure, Dr. Brassard testified that he was independently aware of several of the "Possible Adverse Effects" listed in the IFU when he selected the Magnum for Dr. McCoy. *See* ECF 96-5 at 6, 8, Brassard Tr. 31-32, 37-39. But, defense counsel did not ask Dr. Brassard whether he was aware of the magnitude or the probability of those risks. Nor was Dr. Brassard asked whether he would have selected a different device had he been informed of the magnitude and probability of the risks. Accordingly, on the basis of this summary judgment record, plaintiffs are entitled to the presumption discussed in *Balbos*, 326 Md. at 227, 604 A.2d at 468. At trial, however, Biomet may adduce evidence to rebut this presumption.

d.

For the foregoing reasons, I shall dismiss Count I and Count II to the extent that they are based on a theory of manufacturing defect. But, I shall deny the Summary Judgment Motion to the extent that the Motion is based on theories of design defect and failure to warn.

2. Implied Warranties (Count III) & Express Warranty (Count IV)

Defendant seeks summary judgment as to both Count III and Count IV. ECF 96-1 at 38-40. According to Biomet, plaintiffs' claim for breach of implied warranties fails because the Magnum was not defective and, even if it was, plaintiffs did not notify Biomet of any defect "within a reasonable time" after the defect was discovered. *Id.* at 38. And, Biomet maintains that it "never made any express warranties to Plaintiffs." *Id.* at 39.

In their opposition, plaintiffs do not address these contentions. Yet, they responded to Biomet's arguments as to every other claim. ECF 103 at 11.

According to Biomet, plaintiffs have abandoned their claims in Count III and Count IV. ECF 106 at 1-2. I agree.

In *Canaan Christian Church v. Montgomery Cty., Maryland*, ___ F. Supp. 3d ___, TDC-16-3698, 2020 WL 5849479, at *10 (D. Md. Sept. 30, 2020), *appeal filed*, Judge Chuang quoted *Satcher v. Univ. of Ark. at Pine Bluff Bd. of Trustees*, 558 F.3d 731, 735 (8th Cir. 2009), for the proposition that "'failure to oppose a basis for summary judgment constitutes waiver of that argument.'" Judge Chuang also cited a decision from this district, *Mentch v. E. Sav. Bank, FSB*, 949 F.Supp. 1236, 1247 (D. Md. 1997), in which the court found that "the plaintiff had abandoned a claim 'by failing to address that claim in her opposition to [the defendant's] motion for summary judgment, or to offer clarification in response to [the defendant's] reply brief.'"

Accordingly, I shall grant summary judgment to Biomet as to Count III and Count IV.

3. Punitive Damages (Count V)

The Fourth Circuit has said that "no matter what the theory of recovery, punitive damages cannot be recovered absent malice." *Squal v. BL Ltd.*, 710 F.3d 1027, 1033 (4th Cir. 1983); *see also Darcar Motors of Silver Spring, Inc. v. Borzym*, 379 Md. 249, 265, 841 A.2d 828, 837 (2004);

Owens-Illinois, Inc. v. Zenobia, 325 Md. 420, 601 A.2d 633 (1992). Indeed, under Maryland law, punitive damages may only be awarded in cases of "actual malice," which means ill will, fraud, intent to injure, or evil motive or purpose. *Tierce Md., Inc. v. Williams*, 381 Md. 378, 414 n.29, 849 A.2d 504, 526 n.29 (2004).

To prove actual malice in a products liability case, a plaintiff must establish: "'(1) actual knowledge of the defect on the part of the defendant, and (2) the defendant's conscious or deliberate disregard of the foreseeable harm resulting from the defect.'" *Morris*, 2020 WL 5849482, at *13 (quoting *Zenobia*, 325 Md. at 460, 601 A.2d at 653).

Punitive damages must be established by clear and convincing evidence, a "heightened standard." *Jimenez v. DaimlerChrysler Corp.*, 269 F.3d 439, 450 (4th Cir. 2001) (internal quotation marks omitted). "Clear and convincing evidence" is defined as "evidence . . . of such weight that it produces in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established." *Id.*

Biomet contends that plaintiffs have not carried their burden of demonstrating actual malice by clear and convincing evidence. ECF 96-1 at 42. Defendant asserts: "There is no evidence that Biomet had actual knowledge of a product defect with Dr. McCoy's . . . Magnum and of the danger of the product at the time the product left its possession or control. Furthermore, there is no evidence that armed with actual knowledge, Biomet consciously or deliberately disregarded the potential harm to consumers." *Id.*

In response, plaintiffs do not point to any evidence of actual malice. Rather, they merely incorporate by reference their arguments in earlier briefing about the sufficiency of Count V.

On February 21, 2019, Biomet moved to dismiss the punitive damages claim pursuant to Fed. R. Civ. P. 12(b)(6) or to strike it pursuant to Fed. R. Civ. P. 12(f). ECF 47. Plaintiffs opposed

the motion. ECF 53. The Court did not address the merits of Biomet's motion. Rather, by Order of August 8, 2019, I denied the motion because of ongoing settlement negotiations, without prejudice to defendants' right to refile if the case did not settle. ECF 76.

Now, plaintiffs seek to rely on their argument set forth in their opposition to Biomet's previous motion to dismiss. However, that dispute was focused on the sufficiency of the allegations in the Amended Complaint rather than on the evidence produced in discovery.

Plaintiffs do not identify any evidence that would enable them to survive Biomet's Summary Judgment Motion as to the punitive damages claim. Therefore, I shall grant summary judgment to Biomet as to Count V.

4. Loss of Consortium (Count VI)

Maryland allows a plaintiff to recover for loss of consortium where a personal injury to one's self or one's spouse results in a "loss of society, affection, assistance, and conjugal fellowship" in the marital unit. *Oaks v. Connors*, 339 Md. 24, 37-38, 660 A.2d 423, 430 (1995). However, "[a] loss of consortium claim is derivative of the injured spouse's claim for personal injury." *Owens-Illinois, Inc. v. Cook*, 386 Md. 468, 488, 872 A.2d 969, 981 (2005) (quoting *Oaks*, 339 Md. at 38, 660 A.2d at 430); s*ee also Deems v. W. Md. Ry. Co.*, 247 Md. 95, 114, 231 A.2d 514, 525 (1967) (holding that a claim for loss of consortium arising from physical injury must be asserted simultaneously with an underlying tort action).

Both sides agree that the loss of consortium claim is derivative and that, at this juncture, its fortunes rest with those of plaintiffs' other claims. *See* ECF 96-1 at 42; ECF 103 at 11. And, I have rejected Biomet's Summary Judgment Motion as to Count I and Count II to the extent that the claims are premised on a theory of defective design. Thus, Biomet is not entitled to summary judgment as to Count VI.

C. Plaintiffs' Motion for Partial Summary Judgment

1.

In a kitchen sink approach, Biomet asserted affirmative defenses, some of which are plainly specious. Plaintiffs have moved for partial summary judgment on some of the affirmative defenses that Biomet invoked in its answer to the Amended Complaint. At the outset, I address the affirmative defenses for which the lack of merit is essentially undisputed.

In Biomet's opposition, defendants stated that they are no longer pursuing four of the challenged affirmative defenses and "withdraws them." ECF 102 at 2. Those affirmative defenses are: "statute(s) of limitations and/or repose . . . as well as . . . the applicable doctrines of laches, waiver, estoppel, and/or illegality" (Second Affirmative Defense); res judicata (Third Affirmative Defense); lack of standing (Fifth Affirmative Defense); "no legal relationship or privity with Plaintiff" (Fifteenth Affirmative Defense). ECF 48 at 49, 51; *see* ECF 102 at 2. Therefore, I shall grant Plaintiffs' Motion as to these defenses.

The introduction to Plaintiffs' Motion states that they seek summary judgment as to Biomet's Thirty-First Affirmative Defense. ECF 102 at 2. That defense states: "Plaintiffs' claims are barred by the doctrine of implied preemption to the extent that they are premised on alleged misrepresentations or misstatements to the FDA. *See Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001)." However, Plaintiffs' Motion does not contain any argument as to this affirmative defense. And, plaintiffs have not replied to defendants' opposition, as noted. Accordingly, I shall deny Plaintiffs' Motion as to the Thirty-First Affirmative Defense.

I turn to the disputed affirmative defenses.

2. State of the Art (Ninth Affirmative Defense)

Biomet's Ninth Affirmative Defense invoked defendants' "compliance with the state of the art, industry standards, and/or applicable government statutes and regulations." ECF 48 at 50. Although both sides offer succinct definitions of "state of the art," neither fully explains the function of the state of the art defense. *See* ECF 97 at 6-7; ECF 102 at 3-6.

Maryland case law indicates that state of the art evidence may be used to defend failure-to-warn claims. *ACandS, Inc. v. Asner*, 344 Md. 155, 165–66, 686 A.2d 250, 255 (1996), is instructive. There, the Maryland Court of Appeals stated, *id.* (first bracket added):

> The role of state of the art evidence under Maryland law in strict liability, failure to warn cases was explained in *Owens–Illinois, Inc. v. Zenobia*, 325 Md. 420, 432–38, 601 A.2d 633, 638–41, *reh'g denied*, 325 Md. 665, 602 A.2d 1182 (1992). . . . [W]e recognized in *Zenobia* that a majority of courts hold, expressly or implicitly, "that a manufacturer of a product, which is defective only because of the lack of an adequate warning, is not liable when the failure to warn resulted from an absence of knowledge of the dangerous quality of that product." *Id.* at 433, 601 A.2d at 639. But, "the required knowledge can be established by evidence that the dangerous quality of the product should have been known by a manufacturer because it was known in the scientific or expert community." *Id.* "[E]vidence concerning the presence or *absence* of knowledge in the expert community is called 'state of the art' evidence." *Id.* at 435, 601 A.2d at 640 (emphasis added).

However, *Asner* did not discuss state of the art evidence in the context of a claim of defective or negligent design. *See id.* at 165-68, 686 A.2d 254-56. Likewise, decisions of the federal courts applying Maryland law appear to indicate that state of the art is pertinent only to failure-to-warn claims. *See Lohrmann*, 782 F.2d at 1164 ("It appears that in Maryland, state of the art can be considered in a strict liability tort case where the claimed defect is a failure to warn."); *Shreve*, 166 F. Supp. 2d at 413–14 ("There must be evidence that the defendant knew or should have known of the danger posed by the product for there to be a duty to warn of such danger. . . . A manufacturer is "held to the knowledge of an expert in the field" and "at a minimum, he must keep abreast of scientific knowledge, discoveries, and advances." . . . . "[T]he evidence concerning

the presence or absence of knowledge in the expert community is called 'state of the art' evidence.") (internal quotation marks and citations omitted).

Plaintiffs rely on Ms. Truman's opinion that by 2004, MoP was the "gold standard" design for hip implants. ECF 97; *see* ECF 103-6 at 87. Biomet counters with its own expert evidence. ECF 102 at 5. The report of Dr. Kurtz asserts: "MOM bearings were widely used in orthopaedics worldwide in the mid-2000s because they were recognized to substantially reduce the wear rate of arthroplasties. In the United States, the usage of MOM bearings peaked in 2008 after reaching up to 40% of primary hip implants used nationwide." ECF 102-2 at 22.

The conflict between the two expert opinions establishes a genuine issue of material fact. *See Johnson*, 754 F.3d at 562 ("[D]istrict courts are admonished not to weigh or assess the correctness of competing expert opinions."). Accordingly, I shall deny Plaintiffs' Motion with regard to the Ninth Affirmative Defense.

3. Contributory Negligence and Misuse (Twelfth and Thirteenth Affirmative Defenses)

Biomet's Twelfth Affirmative Defense invokes "the doctrine of comparative fault." ECF 48 at 51. Plaintiffs do not cite any law in their discussion of this affirmative defense, perhaps because "Maryland law does not recognize comparative negligence." *Franklin v. Morrison*, 350 Md. 144, 167, 711 A.2d 177, 189 (1998).

But, Biomet discusses the doctrine of contributory negligence under Maryland law. "Maryland law is grounded in contributory negligence principles." *Carter v. Wallace & Gale Asbestos Settlement Tr.*, 439 Md. 333, 348, 96 A.3d 147, 155 (2014). Accordingly, I shall construe the Twelfth Affirmative Defense to invoke contributory negligence.

In Maryland, "'[c]ontributory negligence is the neglect of the duty imposed upon all individuals to observe ordinary care for their own safety. It is the doing of something that a person

of ordinary prudence would not do, or the failure to do something that a person of ordinary prudence would do, under the circumstances.'" *Berkenfeld v. Lenet*, 921 F.3d 148, 153 (4th Cir. 2019) (quoting *Baltimore Gas & Elec. Co. v. Flippo*, 348 Md. 680, 705 A.2d 1144, 1155 (1998)) (brackets in *Berkenfeld*); *see Miller v. Michalek*, 13 Md. App. 16, 19, 281 A.2d 117, 118 (1971); *Campfield v. Crowther*, 252 Md. 88, 93, 249 A.2d 168, 172 (1969).

Proof of a plaintiff's contributory negligence "operates as a complete bar to recovery." *Berkenfeld*, 921 F.3d at 153; *see Coleman v. Soccer Ass'n of Columbia*, 432 Md. 679, 690, 69 A.3d 1149, 1155 (2013); *Kassama v. Magat*, 136 Md. App. 637, 657 767 A.2d 348, 359 (2001), *aff'd*, 368 Md. 113, 792 A.2d 1102 (2002). "The focus of the contributory negligence defense . . . 'is whether the plaintiff took appropriate precautions to protect his [or her] own interests.'" *Kassama*, 368 Md. at 127, 792 A.2d at 1110 (internal citation omitted).

The Fourth Circuit has noted, *Berkfenfeld* at 153 (quoting *Coleman*, 432 Md. at 691, 69 A.3d at 1156):

> Maryland courts have recognized that the doctrine of contributory negligence provides "harsh justice to those who may have acted negligently, in minor ways, to contribute to their injuries, and absolve those defendants from liability who can find any minor negligence in the plaintiffs' behavior."

The Thirteenth Affirmative Defense states: "Plaintiffs' claims are barred to the extent that the injuries alleged in the Complaint were caused by the misuse, abnormal use, or use of the device in a manner not intended by Defendants and over which Defendants had no control." ECF 48 at 51. With respect to the misuse defense, the Maryland Court of Special Appeals has explained: "While misuse of a product is not an 'affirmative defense' to a products liability action, it is a defense in the sense that proof of misuse negates one or more essential elements of a plaintiff's case." *Collins v. Li*, 176 Md. App. 502, 580, 933 A.2d 528, 574 (2007), *aff'd sub nom. Pittway*, 409 Md. 218, 973 A.2d 771. In particular, a defendant might use evidence of misuse of a product

to demonstrate that a plaintiff's actions constituted an intervening or superseding cause of injury. *Id.*; *see also Kline v. ABCO Eng'g Corp.*, 991 F. Supp. 747, 750 (D. Md. 1997) ("'[I]f the Court can say as a matter of law that the plaintiffs' manner of use of the product cut off the chain of proximate causation, the defendant is entitled to summary judgment.' . . . Misuse, which includes failure to follow a manufacturer's warnings, bars recovery for a products liability claim.") (citation omitted) (brackets in *Kline*).

Plaintiffs cite just two pieces of evidence to support their motion as to these two affirmative defenses. First, plaintiffs observe that Dr. Brassard testified that, four months after Dr. McCoy's total right hip replacement, she was doing well and had resumed "normal activities." ECF 97 at 7. It is unclear what significance plaintiffs attribute to this evidence. In addition, plaintiffs cite a snippet of opinion evidence from Dr. Ebert's deposition testimony. However, I have excluded such evidence under Rule 702. *Id.* Plaintiffs also assert: "Biomet offers no evidence that Plaintiff contributed to her injuries in any way, or misused her metal-on-metal device." *Id.* at 8.

Biomet, on the other hand, cites opinion evidence from two of its expert witnesses. In Dr. Kurtz's report, he opined that suboptimal implantation of the Magnum, "combined with Dr. McCoy's history of falling, and, to a lesser extent, her body mass, are significant clinical and patient factors that resulted in the . . . need for revision surgery." ECF 96-13 at 11. And, Dr. Fleeter testified at his deposition that falling could have contributed to the loosening of Dr. McCoy's Magnum. ECF 102-4 at 5. According to Biomet, this evidence presents genuine issues of material fact regarding the role of Dr. McCoy's actions in contributing to her implant's failure. *Id.* at 8.

Biomet has not presented any legal argument or evidence as to how falling might constitute a negligent act or misuse of the Magnum. Without more, Biomet offers no reason why it should

be entitled to pursue these defenses. Accordingly, I shall grant Plaintiffs' Motion as to Biomet's Twelfth and Thirteenth Affirmative Defenses.

4. Spoliation (Thirtieth Affirmative Defense)

Biomet's Thirtieth Affirmative Defense invokes "the doctrine of spoliation and the failure to properly preserve evidence necessary to the determination of the alleged claims against Defendants." ECF 48 at 54.

Spoliation occurs when a party destroys or materially alters evidence or fails to preserve property that could be used as evidence in a pending or reasonably foreseeable case. *See Boone v. Everett*, 751 F. App'x 400, 401 (4th Cir. 2019) (per curiam); *see also Silvestri v. Gen. Motors Corp.*, 271 F.3d 583, 590 (4th Cir. 2001). Federal courts derive the power to sanction spoliation from Fed. R. Civ. P. 37(e) as well as courts' inherent authority to control the judicial process. *See Chambers v. NASCO, Inc.*, 501 U.S. 32, 43-46 (1991); *EEOC v. Performance Food Grp., Inc.*, CCB-13-1712, 2019 WL 1057385, at *2 (D. Md. Mar. 6, 2019) (Gesner, M.J.); *Steves & Sons, Inc. v. JELD-WEN, Inc.*, 327 F.R.D. 96, 103-04 (E.D. Va. 2018); *Victor Stanley, Inc. v. Creative Pipe, Inc.*, 269 F.R.D. 497, 517 (D. Md. 2010). Because a court must exercise its inherent authority with restraint, it will rely on statutory authority whenever applicable. *See Chambers*, 501 U.S. at 44; *Victor Stanley, Inc.*, 269 F.R.D. at 518.

"[S]poliation does not result merely from the 'negligent loss or destruction of evidence.'" *Turner v. United States*, 736 F.3d 274, 282 (4th Cir. 2013) (brackets added). For spoliation to occur, "the alleged destroyer must have known that the evidence was relevant to some issue in the anticipated case, and thereafter willfully engaged in conduct resulting in the evidence's loss or destruction. Although the conduct must be intentional, the party seeking sanctions need not prove

bad faith." *see also Goodman v. Praxair Servs., Inc.*, 632 F.Supp.2d 494, 518 (D. Md. 2009) (setting forth the elements that a party seeking spoliation sanctions is required to prove).

"The duty to preserve material evidence arises not only during litigation but also extends to that period before the litigation when a party reasonably should know that the evidence may be relevant to anticipated litigation." *Silvestri*, 271 F.3d at 591. Even if a party "does not own or control the evidence, he still has an obligation to give the opposing party notice of access to the evidence or of the possible destruction of the evidence if the party anticipates litigation involving that evidence." *Id.*

Under the spoliation doctrine, a court may order dismissal, grant summary judgment, or permit an adverse inference to be drawn against a party in order to "level the evidentiary playing field and for the purpose of sanctioning improper conduct." *Vodusek v. Bayliner Marine Corp.*, 71 F.3d 148, 156 (4th Cir.1995). Circumstances justifying dismissal, however, are rare. In *Silvestri*, 271 F.3d at 593, the Fourth Circuit characterized dismissal as "the ultimate sanction for spoliation" and observed that it "is usually justified only in circumstances of bad faith or other 'like action'" (citation omitted). Further, the Court instructed, *id.*:

> At bottom, to justify the harsh sanction of dismissal, the district court must consider both the spoliator's conduct and the prejudice caused and be able to conclude either (1) that the spoliator's conduct was so egregious as to amount to a forfeiture of his claim, or (2) that the effect of the spoliator's conduct was so prejudicial that it substantially denied the defendant the ability to defend the claim.

See King v. Am. Power Conversion Corp., 181 F. App'x 373, 376 (4th Cir. 2006) (discussing and applying *Silvestri*); *Erie Ins. Exch. v. Davenport Insulation, Inc.*, 659 F. Supp. 2d 701, 708 (D. Md. 2009) (concluding that there were "no feasible sanctions short of dismissal"); *Sampson v. City of Cambridge, Md.*, 251 F.R.D. 172, 180 (D. Md. 2008) (discussing *Silvestri*).

In their motion, plaintiffs do not discuss any of the foregoing case law. Rather, they appear to assume that Biomet's spoliation defense is concerned with plaintiffs' compliance, or lack

thereof, with an order issued by Judge Miller in the MDL proceedings. Plaintiffs cite the "Explant Preservation Order" of March 13, 2013, in which Judge Miller ordered, MDL-2391, Dkt. No. 279 at 2:[13]

> With respect to [Magnum] Devices that have not yet been explanted or have been explanted but are not in either party's possession, counsel for a plaintiff may elect to obtain plaintiff's Explanted [Magnum] Device from plaintiff's surgeon or the hospital where the surgery occurred and send it to a contract laboratory of plaintiff's choice or a designated storage facility. If plaintiff's counsel does not elect to obtain an Explanted [Magnum] Device within 60 days of the revision surgery, Biomet will make arrangements for it to be sent to Malcolm Naylor of Biomet in Warsaw, Indiana.

It is undisputed that the implant is not in the possession of any party to this case and has not been since the remnants of the implant were removed during Dr. McCoy's second revision surgery in 2011. *See id.*; ECF 102 at 10-14. According to plaintiffs, Judge Miller's order did not impose an obligation on them (or on plaintiffs' counsel) to obtain the Biomet device explanted from Dr. McCoy. As a result, they assert that Biomet's spoliation defense necessarily fails.

However, Biomet's spoliation defense is not based upon Judge Miller's order, but rather on the spoliation doctrine. *See* ECF 102 at 8-14. Biomet asserts: "Plaintiffs took no action to try to locate and preserve [Dr. McCoy's] right hip explant prior to retaining counsel, despite Dr. McCoy's personal belief that her injuries stemmed from her . . . Magnum device." *Id.* at 11. Since plaintiffs filed suit, Biomet has not been able to obtain the device. As a result, Biomet did not have an opportunity to inspect it, which would have been relevant to the defense of this suit. *Id.* at 12.

[13] The Explant Preservation Order of March 7, 2013, was superseded by the "Amended Explant Preservation Order" of November 24, 2015. MDL-2391, Dkt. No. 3008. The amended order did not change the portion of the order pertinent to the issues here. *See id.*

Biomet cites two pieces of evidence that, in its view, raise questions as to plaintiffs' knowledge of the whereabouts of her removed implant. In a response by plaintiffs to an interrogatory, they stated that the device "was discarded by Union Memorial Hospital prior to MDL formation and prior to engaging an attorney to represent her in this case." ECF 102-6 at 5. And, in response to a request for admission "that . . . the [Magnum] has been destroyed," Dr. McCoy stated: "Plaintiff neither admits nor denies this request. She does not know where the subject device is located, and will not guess about the steps taken by the hospital, or by Biomet and its representatives, to maintain and obtain the explanted device." ECF 102-7 at 3.

In sum, Biomet is of the view that "the evidence and circumstances outlined above generate genuine issues of material fact as to whether Plaintiffs failed in their duty to preserve the right hip device under circumstances evidencing bad faith, willfulness, gross negligence, or ordinary negligence, and whether Biomet has been prejudiced." ECF 102 at 14.

The thrust of Biomet's opposition on this issue is that sanctions against plaintiffs for spoliation might be warranted. What is at issue here, however, is not a motion for sanctions, but rather, an affirmative defense. "An affirmative defense will defeat the plaintiff's claim if it is accepted by the district court or the jury." 5 WRIGHT § MILLER 5, FED. PRAC. & PROC. § 1270 (citing, *inter alia*, *Hartford Fire Ins. Co. v. Annapolis Bay Charters, Inc.*, 69 F. Supp. 2d 756, 758 (D. Md. 1999). In other words, the question is whether plaintiffs are entitled to a judgment that Biomet cannot successfully dismiss some or all of plaintiffs' claims on the basis of a spoliation defense.

Under the circumstances here, I am of the view that Biomet cannot so prevail. In a footnote, ECF 102 at 14 n.6, Biomet suggests that dismissal might be warranted here, and it cites to *Silvestri*, 271 F.3d at 594-95. But, *Silvestri* was a very different case. There, the plaintiff's product liability

suit against General Motors Corporation arose out of a car crash during which the airbags in the plaintiff's car "did not deploy as warranted." *Id.* at 585. The plaintiff did not give General Motors Corporation notice of his claim or an opportunity to inspect the vehicle before it was repaired. *Id.* The district court dismissed the suit on spoliation grounds, concluding that the car was "'the sole piece of evidence'" in the case. *Id.* (citing the district court decision). The Fourth Circuit affirmed, reasoning that the defendant was deprived of access to "the only evidence from which it could develop its defenses adequately." *Id.* at 594.

In contrast, Biomet has mounted a vigorous defense even without Dr. McCoy's Magnum implant. Biomet relies, *inter alia*, on extensive expert evidence as to both general causation and specific causation, medical records, images of plaintiff's hip, testimony from Dr. McCoy, and testimony from her treating physicians, Dr. Brassard and Dr. Ebert. There is no basis for concluding that, if Dr. McCoy's conduct amounted to spoliation, the spoliation "was so prejudicial that it substantially denied the defendant the ability to defend the claim." *Id.* at 593.

Moreover, Biomet's argument is contrary to common sense. To be sure, the "duty to preserve material evidence . . . extends to that period before the litigation when a party reasonably should know that the evidence may be relevant to anticipated litigation." *Silvestri*, 271 F.3d at 591. But, there is no evidence that Dr. McCoy contemplated litigation at the time of her revision surgeries. Indeed, Biomet acknowledges that the existence of evidence suggesting that Dr. McCoy first contemplated litigation "a few months after" her second revision surgery. ECF 102 at 11. And, a patient preparing to undergo hip revision surgery, or recovering from such surgery, might not be focused on ensuring recovery of a hip implant device removed by the surgeon. Understandably, the patient is likely to be focusing on her health and wellbeing, rather than on future litigation.

Therefore, I shall grant Plaintiffs' Motion as to the Thirtieth Affirmative Defense, to the extent that Biomet's spoliation defense seeks dismissal of some or all of plaintiffs' claims. At this juncture, there is no indication that Biomet is "entitled to an adverse inference instruction related to Plaintiff's failure to preserve" Dr. McCoy's Magnum implant. ECF 102 at 15 n.6. However, this ruling does not foreclose the defense from seeking to question plaintiff at trial about the matter.[14]

IV. Conclusion

For the reasons set forth above, I shall grant in part and deny in part Biomet's Shapiro Motion (ECF 94); grant Biomet's Ebert Motion (ECF 95); grant in part and deny in part Biomet's Summary Judgment Motion (ECF 96); and grant in part and deny in part Plaintiffs' Motion (ECF 97).

An Order follows.

Date: January 25, 2021

/s/
Ellen L. Hollander
United States District Judge

[14] Of course, the wisdom of such cross-examination is a matter for defense counsel to consider.